

# EXHIBIT 36

Sarah E. Kane, M.D.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

-----x  
IN RE: JOHNSON & JOHNSON TALCUM  
POWDER PRODUCTS MARKETING, SALES  
PRACTICES, AND PRODUCTS MDL NO:  
LIABILITY LITIGATION 16-2738 (FLW)(LHG)

-----x  
THIS DOCUMENT RELATES TO  
ALL CASES

-----x  
DEPOSITION UNDER ORAL EXAMINATION OF  
SARAH E. KANE, M.D.

January 25, 2019, 9:19 a.m.

- - -

REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

- - -

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1	1 APPEARANCES: (Continued)
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5	975 F Street, N.W.	5	fallopian tube injury, and serous
6	Washington, D.C. 20004	6	carcinoma development" 91
7	(202) 463-2400	7	Exhibit 10 "Blaustein's Pathology of the Female
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1	<b>E X H I B I T S</b>	
2	Number      Description      Page	
3	Exhibit 25 (Continued)	
4	and ovarian talc particle burden" 308	1 identified yesterday in that list are voluminous
5	Exhibit 26 Article entitled "Pycnogenol reduces	2 and dense and require additional time to cover,
6	Talc-induced Neoplastic Transformation	3 to the extent that they substantively informed
7	in Human Ovarian Cell Cultures" 328	4 Dr. Kane's opinions in this case.
8		5 We'd also like to object to the
9		6 inclusion of those materials on the science day
10		7 presentations, which were not intended for any
11		8 other purpose than for science day in the MDL.
12		9 And that's all I have to say on the
13		10 objections.
14		11 MR. ROTMAN: Go ahead.
15		12 MR. TISI: First of all, as you know,
16		13 many of those documents were documents that were
17		14 provided to counsel in connection with virtually
18		15 every depositions that have been taken to date.
19		16 In fact, it was provided with Dr. Mohrman that
20		17 was being taken at the same time today; it was
21		18 provided with Dr. Zelikoff earlier in the week;
22		19 it was provided almost routinely.
23		20 Many of them -- some of them,
24		21 particularly the Health Canada document, were
25		22 documents that only became available in mid
		23 December, number one.
		24 Number two, I believe that the science
		25 day document that you're referring to, which I
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1	<b>P R O C E E D I N G S</b>	
2	THE VIDEOGRAPHER: We are now on the	1 think you'll find was not relied on in any way,
3	record. My name is Jody Urbati. I am a	2 was a -- that was the California and not the MDL.
4	videographer for Golkow Litigation Services.	3 So I just want to be clear about that.
5	Today's date is January 25, 2019; the time,	4 So there is no prejudice, and we would
6	9:19 a.m.	5 clearly object to -- these are not documents she
7	This video deposition is being held in	6 relied on for her report; they just are
8	Boston, Massachusetts, In Re: Johnson & Johnson	7 supplemental materials. But -- you can ask
9	Talcum Powder Products Liability Litigation in	8 questions, but we will certainly object to
10	the United States District Court for the District	9 reconvening the deposition at any later time. We
11	of New Jersey.	10 made that clear yesterday.
12	The deponent today is Sarah Kane.	11 MS. AHERN: Thank you.
13	Counsel will be noted on the stenographic record.	12 MR. ROTMAN: Yeah, there was -- one of
14	The court reporter is Janet Sambataro and will	13 the documents was a textbook that Dr. Kane first
15	now swear in the witness.	14 looked at two days ago or -- yeah, I think it was
16	(Witness sworn.)	15 two days ago, and so I added it to the list. And
17	MS. AHERN: Just a quick housekeeping	16 she brought the textbook with her today.
18	matter. The defendants would like to lodge an	17 MR. KLATT: Can I just add we had an
19	objection to the additional materials to Sarah	18 agreement for all the other depositions, and I
20	Kane that were served yesterday at 3:36 p.m. by	19 assume we continue today, one objection by a
21	Ashcraft law firm. Serving supplementary	20 party is good for all.
22	materials 24 hours before an expert deposition is	21 MR. TISI: That's fine, yes.
23	prejudicial to the defendants' ability to	22 MR. ROTMAN: And, you know, just so
24	prepare.	23 it's clear to anybody reading the transcript that
25	The number of the documents that were	24 what you received yesterday was the third
		25 reference list that we've provided for Dr. Kane,

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<p>1 the first being with her report in November; the 2 second being on January 4th, which was about ten 3 days before the deposition had been scheduled for 4 January 14th; and then these additional items 5 were materials that either were inadvertently 6 left off or not reviewed until just very 7 recently.</p> <p>8 MS. AHERN: Okay. To the extent that 9 these new materials inform her substantive 10 opinions and were not included in her report or 11 prior versions of the reference list, then we can 12 talk about that later --</p> <p>13 MR. TISI: Yeah.</p> <p>14 MS. AHERN: -- in terms of additional 15 time.</p> <p>16 And just to clarify, Steve, you said 17 that she reviewed one textbook. It looks like on 18 the list that I received, she reviewed the 19 second, fourth, and fifth editions of the 20 textbook --</p> <p>21 MR. ROTMAN: I was referring --</p> <p>22 MS. AHERN: -- or textbooks.</p> <p>23 MR. ROTMAN: I was referring to that as 24 one textbook, yeah, but you're right, the 25 different editions. And she did bring with her</p>	<p>1 Commonwealth Pathology Partners? 2 A. The address we commonly use is 81 3 Highland Avenue, Salem, Massachusetts. It's 4 01970.</p> <p>5 Q. Okay. And do you have any separate 6 consulting business?</p> <p>7 A. No. Other -- outside of this type of 8 medical expert witness work, no.</p> <p>9 Q. Okay. And how often do you do this 10 sort of medical witness work?</p> <p>11 A. I am very new at it. I have done one 12 deposition before in a tobacco case.</p> <p>13 Q. Okay. And the fees that you get from 14 these cases, do they go directly to you or do 15 they go to your -- Commonwealth Pathology 16 Partners?</p> <p>17 A. They go directly to me.</p> <p>18 Q. And, Dr. Kane, you're a medical doctor; 19 correct?</p> <p>20 A. Yes.</p> <p>21 Q. And what is your medical specialty?</p> <p>22 A. I am board certified in anatomic and 23 clinical pathology and cytopathology, with 24 fellowship training in gynecologic pathology.</p> <p>25 Q. Does that mean that you review</p>
<p>1 today those materials.</p> <p>2 MS. AHERN: So she has a copy with her 3 today of all of the items listed in the 4 additional materials to Sarah Kane that was 5 served yesterday.</p> <p>6 MR. ROTMAN: No.</p> <p>7 MS. AHERN: Okay. Do you know what 8 she -- well, we can -- we'll find out.</p> <p>9 MR. ROTMAN: Yeah.</p> <p>10 MS. AHERN: Okay. All right.</p> <p>11 SARAH E. KANE, M.D., 12 having been duly sworn, after presenting 13 identification in the form of a driver's license, 14 deposes and says as follows:</p> <p>15 DIRECT EXAMINATION</p> <p>16 BY MS. AHERN:</p> <p>17 Q. Good morning, Dr. Kane.</p> <p>18 A. Good morning.</p> <p>19 Q. Can you please state your name for the 20 record?</p> <p>21 A. Sure. Sarah Kane.</p> <p>22 Q. And, Dr. Kane, who is your current 23 employer?</p> <p>24 A. Commonwealth Pathology Partners.</p> <p>25 Q. And do you have a business address at</p>	<p>1 diagnostic materials, slides, and blocks that 2 have been taken from patient procedures and make 3 determinations regarding diagnosis?</p> <p>4 A. Yes.</p> <p>5 Q. Do you see patients as part of your 6 medical practice?</p> <p>7 A. Yes. Occasionally, cytopathologists 8 sometimes perform a procedure that's called a 9 fine-needle aspiration. And so if a patient is 10 seen in clinic and the clinician discovers a 11 palpable nodule, I might be asked to go into the 12 room and perform a fine-needle aspiration.</p> <p>13 Q. But you don't see patients in the sense 14 that you don't counsel patients and provide 15 ongoing care for an individual patient?</p> <p>16 A. Well, I mean, I guess my pathology 17 report is part of the -- basically speaks to 18 medical treatment and informs clinical treatment 19 of the patient. So my pathology reports are seen 20 by the patient.</p> <p>21 Q. I guess what I'm getting at is: Do you 22 see patients as part of your practice, give them 23 a history and physical, provide ongoing care for 24 them outside of the setting of a fine-needle 25 aspiration or a specific procedure related to a</p>

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<p>1 diagnosis?</p> <p>2 MR. ROTMAN: Is this working for you?</p> <p>3 THE WITNESS: Oh, I'm sorry?</p> <p>4 MR. ROTMAN: Is it working?</p> <p>5 THE WITNESS: Yes.</p> <p>6 MR. ROTMAN: Okay.</p> <p>7 A. Outside of the fine-needle aspiration setting, the only time I might see a patient would be with a blood transfusion reaction. I might have to go to the floor to examine the patient or patient chart.</p> <p>12 Ongoing care for them outside of the setting of a fine-needle aspiration, the nature of gynecologic pathology, sometimes I will see a Pap smear from a patient and then a cervical biopsy from a patient and then a LEEP from the patient, and I might speak to the clinician about treatment algorithms, that kind of thing.</p> <p>19 Q. Do you actually then go see the patient themselves and discuss with them the results of their Pap smear or other testing?</p> <p>22 A. Typically, no.</p> <p>23 Q. Have you ever performed a history and physical in your practice as a pathologist?</p> <p>25 A. Yes.</p>	<p>1 aspiration, a blood transfusion reaction.</p> <p>2 Are there any others?</p> <p>3 A. I'm trying to think what another possibility might be.</p> <p>5 I mean, I go into the operative room when patients are in surgery sometimes with the surgeon to do intraoperative frozen sections, which are realtime diagnosis while the patient is having a procedure.</p> <p>10 Q. But you're interacting with the physicians in that respect, aren't you, not with the patient?</p> <p>13 A. It can be both.</p> <p>14 MR. ROTMAN: Objection. Objection.</p> <p>15 You can answer.</p> <p>16 MS. AHERN: You can answer.</p> <p>17 A. The vast majority of the time I'm with frozen sections, I'm interacting with the surgeon.</p> <p>20 Q. Are there times where you are interacting with the patient during a surgical procedure?</p> <p>23 MR. ROTMAN: When you say "interacting," you mean having a conversation or do you mean having any kind of contact?</p>
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<p>1 Q. Under what circumstances?</p> <p>2 A. Under blood transfusion reactions.</p> <p>3 Q. And what sort of history and physical do you take in relation to a blood transfusion reaction?</p> <p>6 A. Well, you might be looking at blood pressure and review of the medical chart, temperature, that kind of thing.</p> <p>9 Q. So you review the medical chart.</p> <p>10 Is that medical chart prepared by another physician?</p> <p>12 A. Usually, you're looking at retrospective data at the time of the blood transfusion reaction.</p> <p>15 Q. How often will you see the same patient who has had a blood transfusion reaction?</p> <p>17 A. Not very often.</p> <p>18 Q. Okay. Do you ever counsel patients on risk factors for ovarian cancer?</p> <p>20 A. Have I ever? Probably, but in my day-to-day practice, I'm not seeing patients on a regular basis to do that.</p> <p>23 Q. And the only time you see patients is with regard to specific issues that are within your realm of pathology expertise, a fine-needle</p>	<p>1 MR. KLATT: Steve, just limit the objection to "form."</p> <p>3 MR. ROTMAN: I'm trying to clarify.</p> <p>4 MR. KLATT: It doesn't matter.</p> <p>5 BY MS. AHERN:</p> <p>6 Q. Did you understand --</p> <p>7 MR. KLATT: Object to form.</p> <p>8 Q. -- the question, Doctor?</p> <p>9 A. Let me -- can -- I'm sorry. Can you read it back or --</p> <p>11 Q. You said, "The vast majority of" --</p> <p>12 MR. ROTMAN: She's reading, I think.</p> <p>13 MS. AHERN: I'll withdraw the question and just remind you.</p> <p>15 BY MS. AHERN:</p> <p>16 Q. You said that the vast majority of the time you're interacting with the physicians; correct?</p> <p>19 A. Yes.</p> <p>20 Q. What do you mean by "interacting"?</p> <p>21 A. During the surgery, the surgeon might have me come up to the operative room or the surgeon might come down to look at the tissue, both grossly and under the microscope with me.</p> <p>25 Q. Okay. Under those circumstances, would</p>

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<p>1 you ever speak to the patient?</p> <p>2 A. Usually not.</p> <p>3 Q. And if you -- have you ever spoken to a</p> <p>4 patient when you were reviewing frozen sections?</p> <p>5 A. I might have during rapid reads of</p> <p>6 fine-needle aspirations. So sometimes</p> <p>7 interventional radiologists will do fine-needle</p> <p>8 aspirations if they have to be ultrasound guided.</p> <p>9 So, yes, I'm speaking to patients sometimes in</p> <p>10 that situation and, obviously, when I do</p> <p>11 fine-needle aspirations.</p> <p>12 Q. Okay. But you don't have a group of</p> <p>13 patients that come to you for ongoing care and</p> <p>14 see you in an office setting, do you?</p> <p>15 A. They are basically -- I would say it's</p> <p>16 the equivalent of physician referral. So if a --</p> <p>17 if a clinician is doing a biopsy -- I mentioned</p> <p>18 women with Pap smears and then cervical biopsies</p> <p>19 and then cone LEEP, you know, it's a trajectory</p> <p>20 of care, but it's physician referred for tissue.</p> <p>21 Q. When you say "physician referred," what</p> <p>22 do you -- what do you mean by that? Are you</p> <p>23 interacting with the physician in providing</p> <p>24 advice or recommendations or are you interacting</p> <p>25 with the patients themselves and providing advice</p>	<p>1 A. That's correct. They're not scheduled</p> <p>2 to see me.</p> <p>3 Q. Okay. And so outside of, like you</p> <p>4 mentioned, procedures like a fine-needle</p> <p>5 aspiration, you wouldn't generally see patients</p> <p>6 directly.</p> <p>7 A. The fine-needle aspiration would be the</p> <p>8 only setting where they would have a scheduled,</p> <p>9 allotted slot time with me.</p> <p>10 Q. Okay. Generally speaking, when you're</p> <p>11 reviewing slides, what sort of medical records do</p> <p>12 you have available to you that are relevant to</p> <p>13 your clinical diagnosis?</p> <p>14 A. I have the entire medical record</p> <p>15 available to me, whatever is in the hospital</p> <p>16 system for that patient.</p> <p>17 Q. What do you routinely rely on or review</p> <p>18 as part of your review of slides in terms of</p> <p>19 medical records?</p> <p>20 A. Well, it's very patient dependent and</p> <p>21 very diagnosis dependent, but, for example --</p> <p>22 I'll stick to the example of cervical biopsy. So</p> <p>23 I'll be looking -- if I have a cervical biopsy,</p> <p>24 I'll look to see the patient's history of Pap</p> <p>25 smears, HPV tests, that kind of thing.</p>
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<p>1 or recommendations?</p> <p>2 A. The physicians usually.</p> <p>3 Q. Okay. So I'm asking about patients.</p> <p>4 A. Yeah.</p> <p>5 Q. On a given day -- like what are -- what</p> <p>6 are the days that you're in the office?</p> <p>7 A. Monday through Friday.</p> <p>8 Q. So are there days that you do</p> <p>9 particular tasks, administrative, and then days</p> <p>10 that you do frozen sections or days that you do</p> <p>11 just general pathology reads?</p> <p>12 A. Rarely, I have an administrative day.</p> <p>13 It would be nice to have more, but, typically, I</p> <p>14 am looking at slides the majority of the day.</p> <p>15 I will be doing frozen sections on some</p> <p>16 days, but we have a very collegial atmosphere, so</p> <p>17 I might do冻子 with another pathologist.</p> <p>18 Some days I'm on cytology, so I'm doing the</p> <p>19 fine-needle aspirations, which is either me</p> <p>20 performing the fine-needle aspirations or me</p> <p>21 reading a rapid interpretation that an</p> <p>22 interventional radiologist has performed.</p> <p>23 Q. So on -- in a given week, it's not like</p> <p>24 you have a patient clinic where patients come to</p> <p>25 see you and they're scheduled to see you.</p>	<p>1 Q. Documents that are directly relevant to</p> <p>2 your review of the current pathology; is that</p> <p>3 correct?</p> <p>4 A. For the most part, I would say so.</p> <p>5 Q. In other words, you don't go back</p> <p>6 through all of their physician records or</p> <p>7 gynecologic visits, their primary care physician</p> <p>8 records?</p> <p>9 A. Again, it would depend on the</p> <p>10 situation. I mean, if I have a lung tumor case,</p> <p>11 I'll probably be looking at the radiology, the</p> <p>12 radiology reports, the -- I'll pull up a report</p> <p>13 with a primary care physician to look for smoking</p> <p>14 history, that kind of thing, to put the whole</p> <p>15 piece together for the diagnosis.</p> <p>16 Q. Okay. And, Doctor, you're here today</p> <p>17 to provide a deposition as an expert witness on</p> <p>18 behalf of the plaintiffs; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you said you've given one</p> <p>21 deposition in the past?</p> <p>22 A. Yes, that's correct.</p> <p>23 Q. And what sort of case was that?</p> <p>24 A. That was a tobacco case.</p> <p>25 Q. Were you an expert in that case?</p>

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<p>1 A. Yes. It was an individual causation 2 case. 3 Q. Okay. Were you an expert for the 4 plaintiffs or the defendants? 5 A. For the plaintiffs. 6 Q. And what sort of -- what sort of case 7 was that in terms of the injury that was being 8 alleged? 9 A. It was a patient with lung cancer who 10 was suing a tobacco company. 11 Q. And what was your specific -- what was 12 your opinion in that case? 13 A. That it was highly likely that her long 14 history of smoking caused her lung cancer. 15 Q. So -- and I should have gone over this 16 with you in the beginning, but you're familiar 17 with the deposition rules? 18 A. In general, I think. 19 Q. Okay. You're doing a very good job. 20 And the main things to remember is the two of us 21 will try not to speak over each other so that the 22 court reporter can take a clean transcript down. 23 If you need a break at some time, that's 24 fine, just let me know. All I ask is if there's 25 a question pending, you go ahead and finish the</p>	<p>1 MS. AHERN: You're welcome. 2 BY MS. AHERN: 3 Q. Dr. Kane, I've handed you a copy of 4 your Notice of Deposition for today. 5 Have you seen this document before? 6 A. Yes. 7 Q. When did you see it? 8 A. I believe it was sometime in December, 9 because the original deposition date was 10 January 14th. 11 Q. And, Doctor, do you know whether you 12 produced all of the documents that are responsive 13 to the request in Exhibit 1, your deposition 14 notice? 15 MR. ROTMAN: We've objected to a number 16 of them. And so she's producing -- you should go 17 item by item, I think, if you want to -- I'm 18 going to object otherwise. 19 Q. Doctor, do you know what you brought 20 with you today? 21 A. Yes. We have my -- a copy of my 22 updated CV. We have copies of my invoice. I 23 believe I have a copy of -- oh, right. Sorry. 24 I have pages that I found for the Blaustein 25 second edition, which I don't have the actual</p>
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<p>1 answer to the question and then we'll take a 2 break. 3 If you don't understand a question that I 4 ask you, please don't answer it. Let me know 5 that you don't understand the question or you'd 6 like me to rephrase it and I'll be happy to do 7 that. All right? 8 A. Okay. 9 Q. Okay. And if you answer the question, 10 is it fair for me to assume that you understood 11 it? 12 A. Yes. 13 Q. All right. 14 (Notice of Oral and Videotaped 15 Deposition of Sarah E. Kane and Duces Tecum 16 marked Exhibit 1.) 17 BY MS. AHERN: 18 Q. Doctor, I'm handing you what's been 19 marked as Exhibit No. 1 to your deposition. 20 MS. AHERN: I don't know how many 21 people need copies of these. I don't have that 22 many, but -- 23 MR. TISI: I'll take a copy. Thank 24 you. 25 MR. ROTMAN: Thank you.</p>	<p>1 textbook. I believe I got -- I found this image 2 off of the internet. But I do have the fourth 3 and fifth editions of the Kurman Blaustein's 4 textbook, and I've marked any relevant pages that 5 I reviewed a couple of days ago. 6 MS. AHERN: If you -- 7 MR. ROTMAN: One second. 8 MS. AHERN: It might be easier if you 9 just hand me those and let me take a look. 10 MR. ROTMAN: In addition, there's the 11 boxes in the room that are the documents that 12 were sent up by counsel from Ashcraft &amp; Gerel. 13 MS. AHERN: Thank you. 14 BY MS. AHERN: 15 Q. All right, Doctor. So let's take these 16 in order, I guess. Let's look at your -- 17 MR. ROTMAN: She also has a copy of her 18 report. 19 MS. AHERN: Okay. We'll mark your 20 updated CV as Exhibit No. 2. 21 (Curriculum vitae of Sarah E. 22 Kane, M.D. marked Exhibit 2.) 23 BY MS. AHERN: 24 Q. Do you need a copy in front of you? 25 A. Sure.</p>

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<p>1 Q. Okay. 2 MS. AHERN: I don't know if anyone else 3 needs a copy. 4 BY MS. AHERN: 5 Q. Doctor, Exhibit 2, this is a copy of 6 your current curriculum vitae? 7 A. Yes. January 2019, yes, this is the 8 current. 9 Q. And can you tell me what has been 10 updated since you submitted your report 11 November 15th of 2018? 12 A. I believe the only change is that I am 13 now director of cytopathology at North Shore 14 Medical Center, which includes Salem Hospital and 15 Union Hospital, which is in Lynn, Massachusetts. 16 Q. Are there any additional publications 17 that you have included on your updated resume -- 18 or, sorry, updated CV? 19 A. I don't believe so. 20 Q. The only change is that your position 21 has changed to director? 22 A. Yes, of cytopathology. 23 Q. Okay. And you've also brought with you 24 invoices -- 25 A. Yes.</p>	<p>1 June 16th, which is the last date. So it would 2 have been after June 16th, 2017. 3 Q. I'm sorry. Do you remember when you 4 were retained by the plaintiffs to be an expert 5 in this litigation? 6 A. I believe I was contacted by Mr. Rotman 7 in early May of 2017. 8 Q. Okay. Do you know how Mr. Rotman found 9 your name? 10 A. I believe he was referred by a 11 colleague. 12 Q. Do you remember what colleague that is? 13 A. Dr. Paul Michaels. 14 Q. And is Dr. Michaels a pathologist? 15 A. Yes. 16 Q. Where does Dr. Michaels work? 17 A. I actually don't know the name of his 18 group, but he is in Austin, Texas now. 19 Q. Where was he in 2017? 20 A. Austin, Texas, I believe. 21 Q. Okay. Is he a gynecologic pathologist? 22 A. No. 23 Q. What type of pathologist is he? 24 A. He has a cytopathology fellowship, in 25 addition to anatomic and clinical board</p>
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<p>1 Q. -- for your time spent on talc? 2 A. I handed them to her. Yes. 3 MR. ROTMAN: What we handed, I think, 4 is multiple copies, so you can hand one back, I 5 suppose. 6 MS. AHERN: We'll mark as Exhibit 3 to 7 your deposition an invoice for rendered services. 8 (Invoice from Sarah Kane, M.D., 9 for services 5/19 through 7/14 marked 10 Exhibit 3.) 11 MS. AHERN: I can't see a date, but it 12 looks like it covers -- well, let's just have you 13 look at it. 14 BY MS. AHERN: 15 Q. Can you tell me the date range covered 16 by that invoice? 17 MR. ROTMAN: Copy for me? 18 A. Yes. It looks like it is from May 19th 19 to June 16th. That would be -- if this is the 20 first invoice, I believe, that would be of 2017, 21 year 2017. 22 Q. Okay. And, Doctor, was this May 19, 23 2017 -- how long after you were retained did you 24 submit this invoice? 25 A. I wouldn't have sent it until after</p>	<p>1 certification. 2 Q. And how do you know Dr. Michaels? 3 A. We were residents and fellows together. 4 Q. Were you -- fellows where? Mass 5 General? 6 A. At Massachusetts General, yes. 7 Q. Was he in the gynecologic pathology 8 fellowship with you or a different fellowship? 9 A. So my fellowship was kind of 10 interesting. I was, unfortunately, one of the 11 last groups where a combined anatomic and 12 clinical pathology residency was five years. I 13 think the next year after I began residency they 14 dropped it to four years. 15 So my surgical pathology and cytopathology, 16 it was a two-year fellowship. The gyn path and 17 the cytopathology, it was over a two-year period. 18 And the weeks of gynecologic pathology were mixed 19 with weeks of cytopathology, so they spread out 20 the cytopathology fellowship over two years. 21 Paul was a cytopathology fellow the first 22 year of my fellowship, so we did all four years 23 of anatomic and clinical pathology and then the 24 first year of fellowship at the same time. 25 Q. Okay. And looking back at Exhibit 3,</p>

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<p>1 this invoice from May 19, 2017, to July 14 of 2 2017, the first entry looks like it's -- it 3 covers a period of May 19th through July 14th, 4 "Communication with firm regarding talc 5 litigation case, one hour"; is that correct? 6 A. Yes. Sorry. Thank you for correcting 7 me. I saw the last line, 6/16, and figured that 8 was the last day that this covered. But you're 9 correct, it's -- July 14th would have been the 10 last date that this invoice covered. 11 Yes, June 16th I met with Mr. Rotman, 12 Dr. Thompson, and Mr. Soileau -- I don't know how 13 to pronounce his last name. 14 Q. Are they all -- they're all attorneys; 15 correct? 16 A. Correct. 17 Q. Okay. What firm? 18 A. I know Mr. Rotman is with Hausfeld. 19 Dr. Thompson is with Allen Beasley. I don't know 20 for sure where Mr. Soileau is from. 21 Q. You said Mr. Thompson is with Beasley 22 Allen. 23 A. I believe so. I don't remember for 24 certain. 25 Q. And at least during --</p>	<p>1 So those hours overlap a little bit. I 2 mean, I kept track of particular hours so that I 3 could bill accurately, but those two things -- 4 certainly, generating the medical expert report 5 would also include review of medical literature. 6 Q. Okay. So you started on your -- on the 7 draft of your expert report in this case back in 8 May of 2017; is that correct? 9 A. Late May, yes. 10 Q. And did you -- do you remember when you 11 started your review of the medical literature? 12 Would it have been May 20th, as reflected in this 13 invoice, Exhibit 3? 14 A. Yes, I believe so. 15 Q. You also have on here that you spent 16 some time researching electron microscopy 17 experts. 18 A. Yes. 19 Q. Was that at the request of the 20 plaintiffs' counsel? 21 A. Plaintiffs' counsel was looking for 22 additional people because there are very few 23 electron microscopy units in the country and very 24 few expert electron microscopists. 25 I can't remember if they asked me to or I</p>
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<p>1 MR. ROTMAN: It's Ms. Thompson. 2 MS. AHERN: Ms. Thompson. 3 MR. ROTMAN: Or Dr. Thompson. 4 THE WITNESS: Doctor. She's a -- she's 5 a doctor, as well as an attorney. 6 Q. And for this first invoice, you billed 7 \$26,666.67; correct? 8 A. Yes. 9 Q. And you spent a total of 53 hours and 10 20 minutes working on talc-related issues? 11 A. Yes. 12 Q. Seventeen hours and five minutes of 13 that was reviewing the medical literature, expert 14 reports, and testimony; is that correct? 15 A. So this was my first time ever 16 recording any sort of invoice for medical expert 17 witness work, so the review of medical 18 literature, expert reports, and testimony, 19 probably some of that will also be included in 20 the generating of medical expert report, because 21 while I was -- I basically began -- you can see 22 from the dates I pretty much started drafting, 23 taking notes in a draft, around May 28th, which 24 was soon after I did my initial medical 25 literature searches.</p>	<p>1 offered to. It could have been the latter. But 2 I was aware that they were looking for additional 3 people to potentially use electron microscopy. 4 Q. Do you know how plaintiffs intended to 5 use the electron microscopy experts? 6 MR. ROTMAN: Objection. That's going 7 into areas that you're not entitled to, so she's 8 not going to answer that. 9 BY MS. AHERN: 10 Q. Doctor, what sort of electron 11 microscopists were you looking for at the 12 plaintiffs' request? 13 MR. ROTMAN: Same objection. 14 MS. AHERN: I'm not asking her about 15 communications that she had with counsel; I'm 16 asking her what sort of work -- 17 MR. ROTMAN: Your question -- 18 MS. AHERN: -- she did -- 19 MR. ROTMAN: Your question -- 20 MS. AHERN: -- that she was paid for by 21 the plaintiffs' counsel and that's reflected on 22 the invoice that you've submitted here today. 23 MR. ROTMAN: You are asking her what 24 she was doing at plaintiffs' counsel's request. 25 That's unrelated to her --</p>

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<p>1 MS. AHERN: You're -- 2 MR. ROTMAN: -- opinions. 3 MS. AHERN: -- instructing her not to 4 answer the question of, "Doctor, what sort of 5 electron microscopists were you looking for at 6 plaintiffs' request?" 7 MR. ROTMAN: Yes. I'm objecting to 8 that. 9 MR. KLATT: That's not a communication. 10 MS. AHERN: That's not a communication. 11 That is what did she do and what was she looking 12 for. 13 MR. TISI: It's consulting. 14 MS. AHERN: She's sitting here today as 15 a testifying expert. 16 MR. ROTMAN: Understood. She's not 17 going to answer that. 18 BY MS. AHERN: 19 Q. Doctor, did you make any 20 recommendations regarding electron microscopists? 21 A. No, ultimately, I did not give them any 22 names. 23 Q. What electron microscopists were you 24 looking at when you were conducting your 25 research?</p>	<p>1 P-E-T-U-R. 2 Q. N-I-E-, Nielsen? 3 A. I believe so. 4 Q. -S-S-O-N? 5 A. No, -L-S-E-N. 6 Q. Did you speak to Dr. Nielsen about 7 potentially working on the talc litigation? 8 A. I believe I e-mailed him. 9 Q. Do you remember when that occurred? 10 A. It was probably -- I don't remember 11 exactly, but I would imagine it was between 5/22 12 and 6/1 of 2017. 13 Q. And was he interested in doing any talc 14 work? 15 A. He was not interested in doing medical 16 expert witness or consulting work. 17 Q. Did you e-mail anybody else, any other 18 electron microscopists? 19 MR. ROTMAN: So you keep on asking her 20 about the consulting work that she was doing that 21 had nothing to do with her opinions in this case, 22 which is why we're here today. We're not here 23 today for you to take the deposition of her 24 consulting work at that stage on this issue, so 25 that whole area is off limits and I'm instructing</p>
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<p>1 MR. ROTMAN: Again, this is her work 2 on -- as a consultant not relating to her 3 opinions in this case -- 4 Q. Doctor, do you -- 5 MR. ROTMAN: -- so you're not entitled 6 to this information. 7 MS. AHERN: You're instructing her not 8 to answer. 9 MR. ROTMAN: Yes. 10 MS. AHERN: Then instruct her not to 11 answer. 12 MR. ROTMAN: I'm instructing you not to 13 answer. 14 THE WITNESS: Okay. 15 BY MS. AHERN: 16 Q. Doctor, do you know any electron 17 microscopists? 18 A. Yes. 19 Q. Who? 20 A. I know Dr. Gunnlaugur Nielsen at 21 Massachusetts General Hospital. 22 Q. How do you spell Gunnlaugur's name? 23 A. G-U-N-N -- I believe there are two 24 Ns -- L-A-U-G-H-E-R [sic], Nielsen. That's with 25 an S-E-N. But he goes by Petur, which is</p>	<p>1 her not to answer. If you want to continue 2 asking those questions, I'm going to continue to 3 object on the same basis. 4 Q. Doctor, did you contact any electron 5 microscopists who agreed to work on the talc 6 litigation? 7 MR. ROTMAN: Objection. 8 Instruct you not to answer for the 9 reasons previously provided. 10 Q. Doctor, do you know a Dr. Campion? 11 A. I do not. 12 Q. Do you know a Dr. John Godleski? 13 A. I know the name. I do not know him 14 personally. 15 Q. Do you know Bill Welch? 16 A. I know the name. I do not know him 17 personally. 18 Q. Okay. 19 (Invoice from Sarah Kane, M.D., 20 for services 7/28 through 9/12 marked 21 Exhibit 4.) 22 BY MS. AHERN: 23 Q. Doctor, I'm handing you what's been 24 marked as Exhibit 4 to your deposition. 25 Can you tell me what that is?</p>

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<p>1 A. This is probably the second invoice. 2 Again, I don't believe I had it numbered on the 3 actual invoice, but this looks like it would be 4 the second invoice. 5 Q. And what period of time does Exhibit 4 6 cover? 7 A. This covers July 28th to September 12. 8 Q. Is this 2017? 9 A. Yes. 10 Q. And you spent an additional 37 hours 11 and 40 minutes reviewing literature and 12 generating your expert report; is that correct? 13 A. Right. And you'll see I actually 14 combined everything, because it got too 15 complicated to separate them out. And generating 16 the medical expert report was sort of this 17 organic part of reviewing the literature. 18 Q. And the total bill was for \$19,666.67; 19 correct? 20 A. Yes. 21 Q. Okay. Was all your time on Exhibit 4 22 spent working on your MDL report? 23 A. I'm sorry. This invoice? 24 Q. Yes, ma'am. Was the time spent on 25 Exhibits 3 and 4, these first two invoices, was</p>	<p>1 Q. Who's been your primary contact? 2 A. Mr. Rotman. 3 Q. Okay. And a total for that bill was 4 \$13,835; is that correct? 5 A. Yes. 6 (Invoice from Sarah Kane, M.D., 7 for services 2/23/18 through 8/3/18 marked 8 Exhibit 6.) 9 BY MS. AHERN: 10 Q. I'm handing you what's been marked as 11 Exhibit 6 to your deposition. 12 Can you tell me what that document is, 13 please? 14 A. So this -- I'm counting now -- looks 15 like this is the fourth invoice -- yes, the 16 fourth invoice that I sent them. 17 Q. And what period of time does this 18 Exhibit 6 cover? 19 A. It looks like February 23rd, 2018, 20 through August 7th, 2018. 21 Q. Okay. And Exhibit 6 reflects that you 22 spent an additional 16 hours and 55 minutes 23 reviewing literature and generating your medical 24 expert report; is that correct? 25 A. Yes.</p>
<p>1 this all in relation to your work on the talc 2 MDL? 3 A. Yes. I'm not involved in any other 4 talc litigation. 5 Q. Okay. 6 MS. AHERN: Okay. I'm marking 7 Exhibit 5 as -- oh, I'm marking, sorry, your 8 third invoice as Exhibit 5 to your deposition. 9 (Invoice from Sarah Kane, M.D., 10 for services 9/18/17 through 2/5/18 marked 11 Exhibit 5.) 12 BY MS. AHERN: 13 Q. This is a copy of an invoice submitted 14 by you; correct? 15 A. Yes. 16 Q. And what dates does it cover? 17 A. This covers September 18th, 2017, to 18 February 5th, 2018. 19 Q. You spent an additional 27 hours and 40 20 minutes working on your report; is that correct? 21 A. Yes. Well, 21 hours, 55 minutes 22 reviewing the literature and the medical expert 23 witness report, and then there were a few hours 24 communicating and meeting with the firm, which 25 would likely be Mr. Rotman.</p>	<p>1 Q. And 3 hours and 30 minutes 2 communicating or meeting with the law firms 3 involved. 4 A. Correct. 5 Q. Okay. And the total for that invoice 6 was \$10,208; correct? 7 A. Correct. 8 Q. Okay. I'm handing you what's been 9 marked as Exhibit 7 to your deposition. 10 (Invoice from Sarah Kane, M.D., 11 for services 9/20/18 through 11/16/18 12 marked Exhibit 7.) 13 BY MS. AHERN: 14 Q. And this is another invoice prepared by 15 you? 16 A. Yes. 17 Q. And the period of time that is covered 18 appears to be September 20th, 2018, through 19 November 16th of 2018; is that right? 20 A. Yes. 21 Q. And you spent an additional 71 hours 22 and 5 minutes reviewing materials and generating 23 your expert report? 24 A. Yes. 25 Q. And about four-and-a-half hours</p>

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<p>1 communicating with the law firms involved?</p> <p>2 A. That's correct.</p> <p>3 Q. For a total of \$37,791.67?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, do you have any -- this takes us through -- this last invoice, Exhibit 7, takes us through November of 2018.</p> <p>6 You've done additional work since November 7 of 2018; correct?</p> <p>8 A. I have.</p> <p>11 Q. Do you know how much time you have yet 12 to invoice or -- sorry, let me back up. Withdraw 13 that.</p> <p>14 Have you sent another invoice to plaintiffs' 15 counsel?</p> <p>16 A. I have not.</p> <p>17 Q. Okay. Do you have any idea how many 18 hours you have yet to invoice?</p> <p>19 A. I have not added it up. I don't really 20 have a ballpark. Maybe -- I would just be 21 guessing. I haven't added it up, to be honest.</p> <p>22 Q. Do you know how much money you've made 23 to date, totaling all of these together?</p> <p>24 MR. ROTMAN: Objection.</p> <p>25 Q. How much money -- how much money have</p>	<p>1 and produce it to one of the attorneys involved?</p> <p>2 A. Sure.</p> <p>3 Q. Thank you.</p> <p>4 MR. ROTMAN: She'll find it if it exists. She'll look for it.</p> <p>6 MS. AHERN: Clearly.</p> <p>7 MR. ROTMAN: She didn't testify that 8 she produced a fee schedule; she said she 9 believed she did.</p> <p>10 MS. AHERN: Understood. If she finds 11 it --</p> <p>12 MR. ROTMAN: Yeah.</p> <p>13 MS. AHERN: -- she'll produce it to you 14 and you'll produce it to us.</p> <p>15 MR. ROTMAN: Exactly.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. Doctor, how much -- I mean, how do you 18 keep track of your time? Do you have a 19 spreadsheet? Do you have some process where you 20 log your hours?</p> <p>21 A. I keep a list, an electronic list.</p> <p>22 It's not an Excel, but it's just a list.</p> <p>23 Q. So is it just a Word document and you 24 put your time entries in and multiply that by 25 your hourly rate?</p>
<p style="text-align: center;">Page 47</p> <p>1 you made in fees associated with your talc work 2 to date?</p> <p>3 A. I would need a calculator to add it all 4 up, but this would be the full amount, all added 5 together.</p> <p>6 Q. And, Doctor, you're charging \$500 an 7 hour; correct?</p> <p>8 A. Yes.</p> <p>9 Q. Did you ask for a retainer when you 10 were initially asked to get involved in the case?</p> <p>11 A. I did not.</p> <p>12 Q. Were you offered a retainer?</p> <p>13 A. It wasn't discussed.</p> <p>14 Q. Does the amount that you charge or your 15 fee, does that change with the activity that 16 you're performing?</p> <p>17 A. No. I think I had a fee schedule where 18 trial might be on a per-day basis, but I don't 19 remember what that is.</p> <p>20 Q. Did you actually submit a written fee 21 schedule to the plaintiffs' counsel?</p> <p>22 A. I believe I did at some point.</p> <p>23 MR. ROTMAN: I don't know. I don't 24 recall that.</p> <p>25 Q. Could you find a copy of that, please,</p>	<p style="text-align: center;">Page 49</p> <p>1 A. Basically.</p> <p>2 Q. And do you generate the invoices 3 yourself?</p> <p>4 A. I do.</p> <p>5 Q. Is that through some sort of program or 6 is this just a Word document that you created and 7 you plug the information in?</p> <p>8 A. It's just a Word document.</p> <p>9 (Discussion off the record.)</p> <p>10 BY MS. AHERN:</p> <p>11 Q. So, Doctor, other than the folders that 12 we've just gone through, is there anything 13 related to your opinions in this case that you 14 did not bring with you to the deposition today?</p> <p>15 MR. ROTMAN: Objection.</p> <p>16 Q. Start with that.</p> <p>17 MR. ROTMAN: Objection.</p> <p>18 A. I believe I brought all of the 19 literature cited in the initial reports. I've 20 tried to be complete, as you know, with listing 21 everything that I've reviewed. It's possible 22 there might have been some things that I reviewed 23 that I forgot to put on a list, but I've tried to 24 be as complete as possible.</p> <p>Q. How did you track your literature</p>

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<p>1 reviews?</p> <p>2 A. So when I was writing the report, 3 you'll notice the first reference list is a list 4 of papers that I actually cited in the text of 5 the report, and then I had -- any papers that I 6 reviewed or other data that I reviewed, I kept in 7 folders on my computer.</p> <p>8 Unfortunately, I had two hard drives 9 malfunction while I was in the process of writing 10 this report. Luckily, I backed up most of it, so 11 it's possible a few things didn't get documented, 12 ultimately, but I really tried my best to make it 13 complete and accurate, and that's why you got 14 another list yesterday.</p> <p>15 Q. Okay. And, I'm sorry, we forgot to 16 mark some of these.</p> <p>17 And so can you tell me -- this is something 18 you brought with you today?</p> <p>19 A. Yes.</p> <p>20 MR. TISI: Can I -- and he's defending 21 the deposition; I just have a little more 22 knowledge of the documents and how they -- at 23 least I think I do.</p> <p>24 I think that in the boxes here are the 25 references cited. The materials considered, I</p>	<p>1 MR. KLATT: Chris, let me just clarify. 2 There's four blue cardboard TLS boxes -- 3 MR. TISI: Correct. 4 MR. KLATT: -- that you're referring 5 to? 6 MR. TISI: Correct. 7 MR. KLATT: And they have binders in 8 them? 9 MR. TISI: They have binders in them. 10 And I haven't even looked at them because they 11 were sent out from the Ashcraft office, but my 12 understanding -- and you can crack them open at 13 break -- but my understanding is there are copies 14 of those. I don't know how many. So it's four 15 boxes, but there are duplicates in there. 16 But they are -- if I understand -- and 17 I can correct them on a break -- if I understand 18 them, they are copies of the references. We did 19 not make copies -- or they did not make copies of 20 the materials that were considered but not 21 referenced in the reports. 22 Do you follow what I'm saying? 23 MR. KLATT: Yeah. What I want to 24 clarify is the four boxes here have not been in 25 Dr. Kane's possession, so there's no notations,</p>
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<p>1 don't think we printed out. I don't think those 2 are in the boxes. And so I don't want there to 3 be any -- there are documents she reviewed that 4 are not here that are not referenced, but were 5 identified in that list.</p> <p>6 Does that make sense?</p> <p>7 MS. AHERN: Maybe. I'm going to go 8 through the various reference lists with her --</p> <p>9 MR. TISI: Okay.</p> <p>10 MS. AHERN: -- and we can kind of 11 clarify as we go.</p> <p>12 MR. TISI: Like, for example, I mean, I 13 just -- I'm just using an example -- we 14 supplemented with some Health Canada materials. 15 I don't know if she brought those with her, 16 because they were not in the original report. 17 They weren't available at the time, so they would 18 not be in the reference materials that are in the 19 binders.</p> <p>20 I know you haven't cracked open the 21 boxes, but I don't want there to be any 22 misimpression. So in terms of what they are, you 23 can certainly ask her, but she may not know what 24 is in the boxes, because we printed them out for 25 her. Do you know what I'm saying?</p>	<p>1 highlighting, stickies -- 2 MR. TISI: Oh, no. 3 MR. KLATT: -- that she -- that 4 Dr. Kane herself would have put on what's in the 5 boxes -- 6 MR. TISI: No. Those were print- -- 7 MR. KLATT: -- is that correct? 8 MR. TISI: Correct. Those were printed 9 out by the plaintiffs' steering committee. 10 Basically, we took her reference list and printed 11 them out for you all. There's no -- there are no 12 notes from her or anything like that. 13 What I don't think we printed out for 14 you would be the extensive documents that she 15 reviewed, including the supplemental materials 16 that were identified, and then put them -- we can 17 provide those in a -- you know, on a thumb drive 18 if you want to. It's just in these depositions 19 we've had so far, half the time the boxes aren't 20 even opened, and we didn't want to just create 21 paper for the purpose of creating paper. But if 22 you want, we can pull those for you and put them 23 in a Dropbox or whatever. 24 I don't want to waste your time, 25 because I do want there to be -- because she</p>

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<p>1 doesn't necessarily know what was printed out for 2 her. 3 MS. AHERN: Understood. So let's -- 4 MR. TISI: I'm sorry if I -- 5 MS. AHERN: That's okay. 6 MR. TISI: -- took up time. 7 (Excerpt from Blaustein's Second 8 marked Exhibit 8.) 9 BY MS. AHERN: 10 Q. Doctor, I'm handing you what's been 11 marked as Exhibit 8 to your deposition. 12 A. Yes. 13 Q. Is this something that you brought with 14 you today in response to the Notice of 15 Deposition? 16 A. It's something I brought because I 17 reviewed it a couple days ago. It probably falls 18 within the deposition. I know you wanted to see 19 everything that I reviewed. 20 Q. So, first of all, tell me what this is. 21 What is Exhibit 8? 22 A. This is a page from Blaustein's second 23 edition of the Pathology of the Female Genital 24 Tract. 25 Q. Do you know what page it is?</p>	<p>1 Q. And, Doctor, the additional materials 2 to -- of Dr. Sarah Kane that were provided to us 3 yesterday, you list "Kurman defense report" from 4 a case by the name of Ristesund. 5 Did you not receive that? 6 A. I asked for -- yeah, I did receive 7 that. 8 Q. You received it? 9 MR. ROTMAN: What she -- what she was 10 saying is she -- 11 MS. AHERN: Wait. I'm asking her the 12 question. 13 Q. Did you receive the report, the Kurman 14 defense report, from a case by the name of 15 Ristesund? 16 A. Yes. I had requested a defense report 17 written by Kurman, if they had anything, and that 18 is what I received. 19 Q. Okay. I thought just a minute ago you 20 said you had not received one because it wasn't 21 available to you. 22 A. I'm talking about the MDL, the curr- -- 23 Q. Ah. 24 A. -- the current defense expert witness 25 reports.</p>
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<p>1 A. Unfortunately, it is cut off. This -- 2 I don't have this textbook. I found this, I 3 think, on Google Books, actually. 4 Q. And so why are you bringing it today 5 again? 6 A. Because I reviewed it. 7 Q. Okay. And why did you review this? 8 A. Well, I recently became aware that 9 Dr. Kurman is a medical expert witness for the 10 defense, so I was more curious. I actually asked 11 the plaintiffs' attorneys for a report -- any 12 report that Dr. Kurman had done, because I was 13 trying to understand his -- what his viewpoint 14 might be. I don't have his defense report 15 because they're not available to us yet, but I 16 was trying to get a sense for what defense 17 medical experts -- their viewpoints. 18 And so I did a search for, basically, "talc" 19 and "Kurman" and I found this (indicating). And 20 then I have two other editions, so I looked 21 through my other editions for any references to 22 talc. Because Kurman edited the fourth and fifth 23 edition. I do not believe he edited the second 24 edition, which is -- this one page is from 25 (indicating).</p>	<p>1 Q. Okay. 2 A. Yeah. 3 Q. Thank you for the clarification. 4 So you have seen at least one defense report 5 that was written by Dr. Bob Kurman; right? 6 A. Yes. 7 Q. And did you -- do you know Dr. Robert 8 Kurman, either personally or by reputation? 9 A. By reputation and I've gone to dinner 10 with him before, but I don't know him well. 11 Q. And what do you know about Dr. Kurman? 12 A. So he is a well-known gynecologic 13 pathologist out of -- he was out of Johns 14 Hopkins. I believe he recently retired. 15 But he certainly edited one of the main 16 gynecologic pathology textbooks and was -- you 17 know, published quite a bit in gynecologic 18 pathology, so his name is well known in our 19 community. 20 Q. And you've actually cited to a number 21 of his papers in your report; correct? 22 A. Yes, I'm sure I have. I know at least 23 one or two. 24 Q. And Dr. Kurman was a Robert Scully 25 fellow, as well, wasn't he?</p>

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<p>1        A. I actually don't remember if he trained      2 under Scully. It's possible. I don't remember      3 whether or not he did.</p> <p>4        Q. Okay. This Exhibit 8 that you brought      5 with you today, are you bringing it here because      6 it mentions granulomatous endometritis caused by      7 foreign bodies?</p> <p>8        A. It says, "Talc may be introduced into      9 the endometrial cavity by instruments      10 contaminated with talcum powder or by gloves      11 during a pelvic examination. Patients may be      12 asymptomatic or may present with menorrhagia.      13 Microscopically, the extent of the granulomatous      14 inflammatory reaction depends on the quantity of      15 the talc inoculated. The infiltrate is      16 characterized by histiocytes and foreign-body      17 multinucleated giant cells surrounded --      18 surrounding the talc crystals, along with      19 lymphocytes and plasma cells. The crystals      20 appear as refractile, birefringent, needle-like,      21 or fan-shaped splinters in polarizing light."</p> <p>22       Q. Are you familiar with the type of      23 reactions -- tissue reactions that are elicited      24 by talc in tissue?</p> <p>25       A. I know -- I'm aware that you can get</p>	<p>1        A. I'm not really sure what you mean by      2 "types." You mean foreign body versus infectious      3 versus --</p> <p>4        Q. Yes.</p> <p>5        A. Those would be the top of the list.</p> <p>6        Q. And are there subtypes of granulomatous      7 inflammation within those categories?</p> <p>8        A. Well, you can have multinucleated giant      9 cells that aren't part of a granuloma.</p> <p>10       You can see -- another common situation      11 where you'll see granulomas is in Crohn's      12 disease. That's granulomatous inflammation in      13 the colon due to inflammatory bowel disease.</p> <p>14       And I think -- yeah. So foreign body and      15 infection are -- and certain diseases that may      16 cause granulomatous -- that's sort of the      17 hallmark of that type of disease, sarcoidosis.</p> <p>18       Q. Have you ever -- the Figure 12.6 in      19 Exhibit 8 actually doesn't have anything to do      20 with granulomatous endometritis, does it?</p> <p>21       A. No. That figure is of a type of      22 finding you can see in the endometrium that's not      23 a granulomatous reaction.</p> <p>24       Q. And how did Exhibit 8, if it does,      25 inform your opinions in this case?</p>
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<p>1        granulomous -- granulomatous inflammation, like      2 here, and you can have acute inflammation, for      3 example, in pleurodesis and chronic inflammation,      4 like lymphocytes and plasma cells.</p> <p>5        Q. Are you an expert in granulomatous      6 inflammation?</p> <p>7        A. Well, I certainly am familiar with      8 the -- with diagnosis of granulomatous      9 inflammation. I see it quite commonly.</p> <p>10       Q. Under what circumstances do you      11 commonly see granulomatous inflammation?</p> <p>12       A. You see it often in -- the most common      13 situation would be foreign-body giant cell. That      14 could be due to foreign bodies or it could be due      15 to -- a common situation we might see them is      16 what's called an epidermal inclusion cyst in the      17 skin, and you actually can get a granulomatous      18 response to keratin that has -- if it's ruptured      19 and gone into the dermis, you can see that.</p> <p>20       Infections is another one. In tuberculosis,      21 you can see granulomatous inflammation. Fungal      22 infections, you can see granulomatous      23 inflammation.</p> <p>24       Q. How many different types of      25 granulomatous reactions are there?</p>	<p>1        A. Well, it was just a piece of      2 information I found, again because I was curious      3 mostly about what Kurman's opinion might be on      4 this litigation. So...</p> <p>5        Q. Does -- do you know what -- did this      6 come from a particular chapter in Blaustein's      7 second edition?</p> <p>8        A. This, I don't -- I have no more      9 information on this particular one. Um --</p> <p>10       Q. Do you know who authored the chapter?      11       MR. ROTMAN: Excuse me. I think she      12 was in the middle of an answer.</p> <p>13       Q. I didn't mean to cut you off. Please      14 go ahead.</p> <p>15       A. Again, I don't have any more      16 information. I brought it because I saw it.</p> <p>17       Q. Okay. So you don't know who authored      18 the chapter that contains this information in      19 Exhibit 8?</p> <p>20       A. Not for this edition, I do not.</p> <p>21       Q. And are you -- do you -- did you say      22 earlier you weren't sure if Dr. Kurman edited      23 this particular version of Blaustein's Pathology?</p> <p>24       A. I don't believe he did. I know he      25 edited the fourth and fifth, but I don't believe</p>

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<p>1 he did the second. 2 Q. Does the information in Exhibit 8 3 inform your decisions regarding talc and 4 causation with regard to ovarian cancer? 5 MR. ROTMAN: Objection. 6 A. It's another piece of evidence. It 7 mentions granulomatous inflammation due to talc 8 in the endometrium. 9 Q. And what does that have to do with 10 ovarian cancer? 11 A. Well, one of the plausible biologic 12 mechanisms for talc causing ovarian cancer is 13 that it elicits a chronic inflammatory reaction. 14 Q. And there are different types of 15 chronic inflammatory reactions, aren't there? 16 A. Yes, there are. 17 Q. Is a foreign-body reaction the same as 18 the type of inflammation seen, for instance, in 19 ulcerative colitis? If you know. 20 A. No, I'm just rereading the question. 21 Ulcerative colitis, you don't typically see 22 foreign-body reaction. 23 Q. Ulcerative colitis is one of the 24 conditions that has been associated with the 25 development of cancer; correct?</p>	<p>1 going to -- 2 MS. AHERN: One second, please. 3 Q. You can see inflammatory conditions 4 that are not in any way linked to the development 5 of cancer; correct? 6 A. So not all chronic inflammation is 7 going to lead to cancer, but chronic inflammation 8 is a well-established cause of different types of 9 cancer. 10 MR. ROTMAN: I'd like to take a break. 11 We've been going a little over an hour. 12 MS. AHERN: Okay. 13 THE VIDEOGRAPHER: Here ends Media 1. 14 Off the record, 10:21 a.m. 15 (A recess was taken.) 16 THE VIDEOGRAPHER: Here begins Media 17 No. 2 in today's deposition of Sarah Kane, M.D. 18 Back on the record, 10:37 a.m. 19 BY MS. AHERN: 20 Q. All right. Dr. Kane, we were -- we 21 left off, we were talking about chronic 22 inflammation and cancer. 23 Do you remember that? 24 A. Yes. 25 Q. Okay. Can you identify for me the</p>
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<p>1 A. Those with ulcerative colitis have an 2 increased risk of colon cancer, yes. 3 Q. Do you know of any particular cancers 4 that have been linked to foreign-body responses? 5 A. Well, foreign-body responses -- for 6 example, asbestos is known to cause an 7 inflammatory response and asbestos is known to 8 cause mesothelioma and lung cancer, and the IARC 9 states that it causes ovarian cancer. 10 Q. And how is the response to asbestos 11 different from the response that's been 12 documented with talc in terms of tissue reaction? 13 A. So you can see a granulomatous reaction 14 to talc. You can see an acute reaction to talc 15 in pleurodesis patients. 16 This page here mentions plasma cells and 17 lymphocytes, which you do see in Crohn's disease. 18 Q. You see plasma cells and lymphocytes in 19 a number of different inflammatory conditions; 20 correct? 21 MR. ROTMAN: You can answer. 22 A. Yes, you can see lymphocytes and plasma 23 cells in inflammatory conditions. 24 Q. And you can see inflammatory con-- 25 MR. ROTMAN: Object -- object -- I was</p>	<p>1 types of ovarian cancer that have been associated 2 with chronic inflammation? 3 A. So we know that endometriosis, as an 4 example, causes an inflammatory response. The 5 types of ovarian cancer that are associated with 6 endometriosis are clear cell carcinoma and 7 endometrioid carcinoma. 8 Q. Are there other forms of ovarian cancer 9 that are associated in the literature with 10 chronic inflammation? 11 A. So we do see chronic inflammation 12 within other types of ovarian cancer, so 13 high-grade invasive serous, low-grade serous 14 carcinoma, you do see chronic inflammation within 15 those tumors. 16 Q. Let me be more precise, because it's 17 sort of a chicken and the egg kind of thing. 18 I'm asking what sort of inflammatory 19 conditions have been associated with the 20 development or the cause of ovarian cancers? 21 A. Yeah. So the mechanisms of a lot of 22 ovarian cancer have been somewhat elusive. 23 Unfortunately, it's a rare disease. It's hard to 24 study. It's difficult to have sort of a large 25 enough cohort to really get good data on ovarian</p>

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<p>1 cancer, and so we don't really know all of the 2 mechanisms of the initiation of ovarian cancer. 3       But we know that chronic inflammation, we 4 see it in ovarian tumors. We know that -- and 5 putting it in a talc perspective, we know that 6 talc can cause chronic inflammation and so -- and 7 we know that chronic inflammation causes other 8 types of cancer.</p> <p>9       Q. So is that -- can you name any other 10 types of ovarian cancers that have been 11 associated in the literature with chronic 12 inflammation in terms of a specific etiology for 13 that cancer?</p> <p>14       A. So, again, I would say I don't know if 15 we can say for certain what the specific etiology 16 is for all types of surface epithelial cancer, 17 but we do know that, again, clear cell has been 18 associated with endometriosis, which causes 19 chronic inflammation, and we see chronic 20 inflammation in tumors. But the mechanisms for 21 these types of tumors have not been completely 22 mechan- -- elucidated.</p> <p>23       Q. So do you not know of any other 24 specific ovarian tumors that have been associated 25 in the literature causally with chronic</p>	<p>1 inflammation, yes. 2       Q. And you would agree that many, if not 3 most, cancers are somewhat proinflammatory. 4       A. I think tumors can be -- can be 5 proinflammatory, yes. 6       Q. So the tumor itself can invoke an 7 inflammatory response during its development; 8 correct?</p> <p>9       A. Some tumors will. 10      Q. And often the tumors will hijack 11 portions of the immune system to help them to 12 grow and metastasize; correct?</p> <p>13      A. I'm not sure exactly what you mean by 14 "hijack," but there are mechanisms to -- or 15 literature to suggest that.</p> <p>16      Q. So just looking at a high-grade serous 17 carcinoma and seeing inflammation doesn't tell 18 you anything about whether that inflammation 19 caused the tumor or whether it was caused by the 20 tumor; is that correct?</p> <p>21      A. So, again, the mechanisms are not that 22 clear, so we don't know for sure. But is all 23 chronic inflammation seen in a tumor the cause of 24 the tumor? I don't know if we know the answer, 25 but, you know, it's definitely an associated</p>
<p>1 inflammation?</p> <p>2       A. Again, I don't believe that the 3 mechanisms of all of these tumors have been 4 elucidated completely.</p> <p>5       Q. And I do understand your answer, but I 6 just want to know if there are -- if you're aware 7 of literature connecting causally chronic 8 inflammation with other types of ovarian cancer 9 other than the two that you've mentioned, 10 endometrioid and clear cell carcinoma.</p> <p>11       A. Well, again, I mentioned that in serous 12 tumors, we do see chronic inflammation in those 13 tumors.</p> <p>14       And with smoking and mucinous ovarian 15 cancers, you know, it's been -- there's some 16 literature that suggests, you know, smoking is 17 associated with mucinous and those -- that can 18 cause inflammatory reactions.</p> <p>19       But, again, this is all -- it's not entirely 20 clear what the etiology of some of these tumors 21 are.</p> <p>22       Q. You mentioned that in high-grade serous 23 carcinoma, you see associated inflammation; 24 correct?</p> <p>25       A. You can see associated chronic</p>	<p>1 pattern that we see with ovarian tumors. 2       Q. So my question is a little different, 3 if I can go back and find it. And it's missing. 4       My question is: As a pathologist looking at 5 slides from a particular patient who has ovarian 6 cancer --</p> <p>7       A. Mm-hmm. 8       Q. -- just the observation that there is 9 inflammatory cells associated with that tumor 10 doesn't tell you anything, as a pathologist, in 11 terms of whether that inflammation caused the 12 tumor or if the tumor caused the inflammation.</p> <p>13       A. Well, I think it depends on the 14 situation. You know, again, for ovarian tumors, 15 if we have a clear cell carcinoma, we could, you 16 know, deduce, especially if you see associated 17 endometriosis, that that is the likely cause, 18 and, again, depending on the patient and the 19 patient's risk factors.</p> <p>20       But, yeah, if you're looking just at one 21 slide without any other information, it would be 22 difficult to say.</p> <p>23       Q. Well, you would never just be looking 24 at one slide, would you? You'd be looking at all 25 of the slides that were available for a</p>

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<p>1 particular patient, which would include 2 diagnostic tissue or tumor tissue, as well as 3 normal, nontumor tissue; correct?</p> <p>4 A. Right.</p> <p>5 Q. Okay. So you would never be in a 6 situation where you're just looking at a single 7 slide and making a determination, unless it's 8 maybe cytology or a biopsy; correct?</p> <p>9 A. I'm sorry. I'm just looking at the --</p> <p>10 Q. Sure.</p> <p>11 A. I'm not sure what the -- the first 12 question came out kind of funny.</p> <p>13 Q. What I was saying is there would never 14 be a situation where you're only looking at a 15 single slide to make a diagnostic determination 16 unless it was from a biopsy sample or a cytology.</p> <p>17 A. That's what I was going to kind of 18 rewind and clarify, that sometimes there is only 19 one slide. So --</p> <p>20 Q. Is that an accurate statement?</p> <p>21 MR. ROTMAN: Let her finish the answer. 22 I think she was saying "so" and then you asked 23 another question.</p> <p>24 A. So in a larger specimen type, it's 25 correct you would be looking, usually, at more</p>	<p>1 MS. AHERN: I'm not finished with my 2 question. You can object when I'm done with my 3 question.</p> <p>4 MR. ROTMAN: I object to you asking a 5 question --</p> <p>6 MR. KLATT: She didn't have -- 7 MR. ROTMAN: -- when she's asking -- 8 MS. AHERN: I can ask a question 9 whenever I want. She doesn't have to answer the 10 question if you instruct her not to, but while 11 she's spending time looking through her report, 12 I'm going to ask her a different question based 13 on her recollection.</p> <p>14 MR. ROTMAN: Well, you've asked her a 15 question, she's in the process of answering it, 16 and you're asking -- you're asking her a second 17 question. That's what I'm objecting to.</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Doctor --</p> <p>20 MR. ROTMAN: Let her finish --</p> <p>21 Q. -- can you answer the question without 22 looking at your report?</p> <p>23 A. Well, I'd like to refer to my report if 24 you're asking questions.</p> <p>25 Q. And that's fine. My only question,</p>
<p style="text-align: center;">Page 71</p> <p>1 slide if there's more tissue that would fit in 2 one cassette to make one slide.</p> <p>3 Q. Let's talk about high-grade serous 4 carcinoma.</p> <p>5 High-grade serous carcinoma is the most 6 common form of ovarian cancer; correct?</p> <p>7 A. It's most -- yes.</p> <p>8 Q. By far the most common form of ovarian 9 cancer; is that also correct?</p> <p>10 A. It's the most common form, yes.</p> <p>11 Q. So let's talk about high-grade serous 12 carcinoma in the context of chronic inflammation. 13 Do you know of any published literature that 14 connects chronic inflammation causally with the 15 development of high-grade serous carcinoma?</p> <p>16 A. I can -- in my report, I actually do 17 have a section. Let me find it.</p> <p>18 MR. ROTMAN: It might be easier to take 19 off the clip, if that helps you flip the pages, 20 because it's two-sided.</p> <p>21 Q. Doctor, while you look for that, just 22 to the best of your recollection, do you remember 23 reading any studies that concluded that --</p> <p>24 MR. ROTMAN: I object. She's in the 25 middle of answering --</p>	<p style="text-align: center;">Page 73</p> <p>1 really, was, just based on your recollection as 2 we sit here discussing chronic inflammation and 3 ovarian cancer, if you are aware of studies that 4 causally associate chronic inflammation with 5 high-grade serous carcinoma?</p> <p>6 A. So there's definitely literature that 7 has looked at associations between chronic 8 inflammation and the resulting sort of 9 expressions.</p> <p>10 And that's what -- I was trying to point you 11 to my report on Page 12, the end of it, where it 12 says, "There also is evidence that talc induces 13 macrophage TNF alpha expression and macrophages 14 that express TNF alpha promote ovarian tumor 15 genesis. TNF alpha is involved in chronic 16 inflammation and induces mutations in vitro and 17 TNF alpha-induced chromosomal mutations occur 18 mostly in cells with P53 aberrations and, of 19 note, high-grade serous carcinomas typically have 20 inactivating mutations in P53."</p> <p>21 So, again, we don't know all the mechanisms 22 of all of these tumors, but there's certainly 23 literature that is investigating those types of 24 associations.</p> <p>25 MR. KLATT: Object. Nonresponsive.</p>

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<p>1           MS. AHERN: Same.</p> <p>2           Q. But since you brought it up, on Page 12</p> <p>3 of your report, can you translate for me that</p> <p>4 paragraph that you just read and put it in lay</p> <p>5 terms and explain how that has anything to do</p> <p>6 with causal associations with ovarian cancer and</p> <p>7 chronic inflammation caused by talc?</p> <p>8           MR. ROTMAN: Objection.</p> <p>9           A. Well, I think it's there in the report.</p> <p>10 If talc is inducing macrophage TNF alpha</p> <p>11 expression and macrophages that express TNF alpha</p> <p>12 can promote ovarian tumor genesis that occur</p> <p>13 mostly in the -- TNF alpha-induced chromosomal</p> <p>14 mutations occur mostly in cells with P53</p> <p>15 aberrations, I think that's relevant in looking</p> <p>16 at evidence that -- for a plausible mechanism</p> <p>17 that inflammation caused by talc can cause</p> <p>18 aberrations in -- can cause P53 aberrations. And</p> <p>19 we know that high-grade serous carcinomas, many</p> <p>20 of them have P53 mutations.</p> <p>21           Q. And high-grade serous carcinomas with</p> <p>22 P53 mutations, what causes the P53 mutations?</p> <p>23           A. Well, again, the literature is still</p> <p>24 evolving into all of the mechanisms regarding</p> <p>25 this. Some of them we know are sort of aberrant</p>	<p>1 genomic event in the development of high-grade</p> <p>2 serous carcinoma?</p> <p>3           A. So, again, I don't know if I -- I don't</p> <p>4 know if we always know what the earliest</p> <p>5 identifiable genomic event in the development of</p> <p>6 high-grade serous carcinoma is.</p> <p>7           Q. Have you reviewed the literature on</p> <p>8 high-grade serous carcinoma from a molecular</p> <p>9 genetics perspective?</p> <p>10          A. Yes, I reviewed papers on molecular</p> <p>11 genetics, yes.</p> <p>12          Q. Do those papers indicate that one of</p> <p>13 the earliest, if not the earliest, genomic event</p> <p>14 in the development of high-grade serous carcinoma</p> <p>15 that has been identified are mutations in P53?</p> <p>16          A. So, again, you can see P53 mutations,</p> <p>17 for example, in the fallopian tubes and you can</p> <p>18 have sort of serous tubal intraepithelial</p> <p>19 carcinomas in the fallopian tube, which are</p> <p>20 thought to be early precursors for high-grade</p> <p>21 carcinoma.</p> <p>22          Q. High-grade serous carcinoma?</p> <p>23          A. Mm-hmm. Sorry, high-grade serous</p> <p>24 carcinoma.</p> <p>25          Q. And do you agree that the STIC lesions</p>
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<p>1 mutations, and we don't always know why they</p> <p>2 occur.</p> <p>3           We know that women with BRCA1 and BRCA2</p> <p>4 mutations have -- can get high-grade -- have a</p> <p>5 higher risk of high-grade serous carcinoma.</p> <p>6           But, again, I don't think we know all of the</p> <p>7 mechanisms that cause, you know, all of these</p> <p>8 tumors.</p> <p>9           MS. AHERN: Objection. Nonresponsive.</p> <p>10          Q. Doctor, do you know, as we sit here</p> <p>11 today, what causes P53 mutations in high-grade</p> <p>12 serous carcinoma?</p> <p>13          A. I think I answered that. We know, I</p> <p>14 mean, what's in my report and women with BRCA1</p> <p>15 and BRCA2 mutations. But, again, the literature</p> <p>16 is evolving with this.</p> <p>17          Q. Doctor, are you suggesting that BRCA1</p> <p>18 and -2 mutations cause P53 mutations in</p> <p>19 high-grade serous carcinomas?</p> <p>20          A. What I'm saying is that we know that</p> <p>21 BRCA1 and BRCA2 mutation patients have a high</p> <p>22 risk of ovarian cancer.</p> <p>23          And so you're asking me what causes, so, you</p> <p>24 know, I'm telling you the data that we have.</p> <p>25          Q. What is the earliest identifiable</p>	<p>1 or serous tubal epithelial carcinomas in the</p> <p>2 fallopian tubes are currently known to be the</p> <p>3 earliest manifestation of high-grade serous</p> <p>4 carcinoma?</p> <p>5           A. Well, it depends on what you mean by</p> <p>6 "manifestation." I mean, it takes a period of</p> <p>7 time from initial insult until we can recognize</p> <p>8 something histologically as a precursor to</p> <p>9 cancer.</p> <p>10          Q. That was -- you're right, that was a</p> <p>11 bad question.</p> <p>12          Do you recognize serous tubal</p> <p>13 intraepithelial carcinomas as an in situ serous</p> <p>14 carcinoma?</p> <p>15          A. I think evidence is supportive of</p> <p>16 serous tubal intraepithelial carcinomas being a</p> <p>17 precursor to some high-grade serous carcinomas.</p> <p>18          Q. And when you say "precursor," do you</p> <p>19 mean a frank cancer or a premalignant lesion?</p> <p>20 What do you mean by "precursor"?</p> <p>21          A. Well, again, not -- we don't know if</p> <p>22 all STICs are going to become high-grade serous</p> <p>23 carcinomas. STICs were originally discovered in</p> <p>24 looking at fallopian tubes of BRCA1 and BRCA2</p> <p>25 patients that had -- what's the word I'm looking</p>

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<p>1 for? -- prophylactic salpingectomies to decrease 2 their risk of ovarian cancer. 3 And that was -- you know, they had evaluated 4 these precursor lesions, and so the thought is 5 that when you have these atypical cells in the 6 fallopian tube fimbria that are -- that have P53 7 aberrations, that that -- the belief is that 8 that's a precursor to some of the serous invasive 9 carcinomas that we see. 10 Q. Do you consider STIC lesions to be 11 carcinomas? 12 A. They're -- the name is intraepithelial 13 carcinoma, so its analogous term would be sort of 14 an in situ cancer. 15 Q. It is a cancer; correct? 16 A. Well, they're calling them 17 intraepithelial carcinomas because they have -- I 18 mean, it's sort of semantics. They have a P53 19 mutation and they're recognizable histologically. 20 Q. Do you agree that they're carcinomas or 21 cancer? 22 A. I certainly agree that they can be 23 precursors to invasive serous carcinomas. It's 24 sort of semantics, precursor -- it -- it's -- 25 it's sort of the same question as ductal</p>	<p>1 that ovulation event, you might end up with 2 precursors. 3 We don't really have a model in a lot of 4 ovarian cancers where you can follow a precursor 5 all the way through to -- what we think is a 6 precursor all the way through to the final tumor. 7 We just -- we don't really have a lot of data on 8 those in-between steps. 9 So it was very, very interesting when they 10 discovered these STIC lesions in the fallopian 11 tube fimbria that had P53 mutations. It was 12 pretty compelling that these might be the 13 precursor lesions to serous -- high-grade serous 14 carcinomas. 15 Now, are all high-grade serous carcinomas 16 caused by STIC lesions or are they all -- is a 17 STIC lesion a precursor to all serous -- 18 high-grade serous carcinomas? I don't think we 19 know that. 20 Q. Do you know of any data associating 21 high -- excuse me, associating chronic 22 inflammation or injury with the development of 23 STIC lesions? 24 A. So, again, I think the literature is 25 still evolving with this -- these STIC lesions.</p>
<p>1 carcinoma in situ in the breast. There's 2 literature that debate about is ductal carcinoma 3 in situ a true cancer or is it a risk factor for 4 cancer, and what is the meaning of treatment for 5 DCIS in the breast? And I would say that that's 6 sort of analogous to STIC lesions in the 7 fallopian tube. 8 Q. Okay. Do you agree that most 9 high-grade serous carcinomas arise from the 10 endometrial cells in the fallopian tube? 11 A. High-grade -- 12 Q. Epithelial cells in the fallopian tube. 13 Excuse me. 14 A. So, again, we -- this was something 15 that the medical community really struggled with, 16 trying to find the precursor lesions to a lot of 17 these tumors. 18 And for a lot of years it was thought that 19 maybe serous carcinomas derived from what are 20 called epithelial inclusion cysts, so, basically, 21 the thought was that during ovulation, you're 22 disrupting the surface epithelium of the ovary 23 and when the ovary sort of heals itself, you get 24 this invaginated epithelium within the ovary and 25 that maybe because of inflammatory response to</p>	<p>1 Q. Sorry. Were you finished? I don't 2 want to interrupt you if you're thinking. 3 A. No, I'm thinking. 4 Again, I don't think we really have the data 5 on where these STIC lesions are coming from. 6 Q. As part of your literature review for 7 your MDL report, did you search specifically for 8 papers that might be linking or associating 9 chronic inflammation with early precursor lesions 10 to serous invasive carcinomas or high-grade 11 serous carcinomas? 12 A. I was certainly looking for literature 13 with the association of inflammation with ovarian 14 cancer. 15 Q. With -- did you look specifically at 16 the various subtypes of ovarian cancer? 17 A. Yes. 18 Q. Is there a particular subtype of 19 ovarian cancer that you think is associated with 20 talc use? 21 A. So most of the epidemiology literature 22 show the highest association with high-grade 23 serous invasive carcinoma. 24 Q. When you say "highest association," are 25 you talking about strength of association?</p>

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<p>1       A. I'm talking about the -- for example, 2 on the cohort studies, they found an association 3 with high-grade serous carcinoma.  4       And in a lot of the case-control studies, 5 when they looked at tumor subtype, a lot of those 6 tumors were serous carcinomas. Now, some of them 7 broke them out by relative risk by subtype; some 8 of them didn't. I'd have to look at the papers.  9       Q. Do you remember which cohort study 10 found an association with high-grade serous 11 carcinoma?  12      A. I believe the Nurses' Health Study. 13 I'd have to look at it to see the numbers.  14      Q. Was there more than one cohort study 15 that you recall associated talc use with 16 high-grade serous carcinoma?  17      A. I'd have to look at them just to be 18 sure, but the one that I remember is the Nurses' 19 Health Study.  20      Q. Are there any other subtypes, 21 histologic types, of ovarian cancer that you 22 believe are associated with talc use?  23      A. Well, I think talc use -- I think talc 24 use could be associated with the -- any type of 25 surface epithelial cancer. That seems to bear</p>	<p>1       A. So I think the most consistent finding 2 is with high-grade serous carcinoma, but there's 3 data for the other types of surface epithelial 4 carcinomas.  5       Q. And what are the surface types of 6 carcinomas?  7       A. So they're endometrioid and clear cell, 8 and mucinous less so than, I believe, the 9 endometrioid and clear cell, although I believe, 10 again, in the 2010 Nurses' Health -- is that -- 11 I'd have to go back -- I -- there was a mention 12 of mucinous -- I'm not absolutely sure it was the 13 Gates 2010, but there was a mention of an 14 increased risk of mucinous in one of those 15 studies.  16      Q. Do you agree that the different 17 histologic subtypes of epithelial ovarian cancer 18 are likely to have different genetic causes?  19      A. I know they're associated with 20 different genetic mutations.  21      Q. Do they develop along distinct 22 molecular genetic pathways?  23      A. That's what the literature suggests at 24 this point.  25      Q. Do they behave differently?</p>
<p>1       out in the epi data. They've certainly seen an 2 association with different types of surface 3 epithelial cancers in the epi data, the strongest 4 association being with the serous invasive.  5       Q. Have you seen any data supporting an 6 association with talc use and a low-grade serous 7 carcinoma?  8       A. I'd have -- again, I'd have to look at 9 the different studies to break it out, but I know 10 there was a study that found an increased risk 11 with serous borderline carcinomas. I'd have to 12 look through the individual data sets.  13      Q. And serous borderline -- are -- serous 14 borderline tumors are not carcinomas; correct?  15      A. Sorry. I -- serous borderline tumors, 16 yes. I misspoke.  17      Q. And you don't remember what study that 18 was that associated talc use with serous 19 borderline tumors?  20      A. I would have to look at the data -- or 21 the study.  22      Q. So do your opinions in this case apply 23 equally to all histologic subtypes of ovarian 24 cancer or are there specific subtype or subtypes 25 that you are opining are caused by talc?</p>	<p>1       A. So the high-grade surface epithelial 2 carcinomas have a more aggressive pathway or 3 presentation. The low-grade surface endothelial 4 carcinomas tend to have a more indolent 5 progression.  6       Q. You've used the term "surface 7 epithelial carcinomas" and I haven't seen that 8 term generally used in the literature.  9       When you talk about surface epithelial 10 carcinomas, are you talking about serous or are 11 you talking about endometrioid or are you talking 12 about clear cell? Mucinous?  13      A. Epithelial carcinomas.  14      Q. That would encompass all of those, 15 wouldn't it? Wouldn't surface epithelial 16 carcinomas encompass mucinous, clear cell, 17 endometrioid, and serous subtypes? They're all 18 epithelial ovarian cancers; correct?  19      A. Yes. That's what I'm referring to when 20 I -- because we also have germ cell tumors and 21 stromal tumors of the ovary. Those are much more 22 rare, and I'm not -- you know, I don't think 23 there's associations with those. So, yes, we're 24 talking about epithelial carcinomas, to be clear.  25      Q. Well, and just -- because I want to</p>

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<p>1 make sure your testimony is also clear. 2 So if we could, if you could use the 3 specific subtype names, like serous or 4 endometrioid -- 5 A. Okay. 6 Q. -- or clear cell. That way there's no 7 confusion later on about what you intended. 8 So when you say -- let's see. Let me go 9 down. Sorry. 10 When you say "high-grade surface epithelial 11 carcinomas," are you talking about high-grade 12 serous carcinomas? 13 MR. ROTMAN: Objection. You're asking 14 her to reflect back on all of her prior answers 15 to all of your prior questions, whether she was 16 referring to the same thing in each one? 17 Q. Do you understand my question? 18 A. I'd have to figure out what answer 19 you're talking about, but -- 20 Q. So you just -- just a few questions 21 ago, you answered -- I said, "Do the different 22 types -- histologic types develop along the same 23 molecular genetic pathways?" 24 You said, "That's what the literature 25 suggests at this point."</p>	<p>1 Does that make sense? 2 A. Okay. Yes. Okay. 3 Q. Okay. All right. So let me ask my 4 question that I asked a little while ago, and 5 you tell me -- you can answer it again with the 6 terminology. 7 Do the different histologic subtypes of 8 ovarian cancer behave differently? 9 A. Yes. Again, the high-grade ones 10 generally behave differently than the low-grade 11 ones. 12 Q. Okay. Do endometrioid and clear cell 13 carcinomas behave differently from high-grade 14 serous carcinomas? 15 A. The high-grade serous carcinomas tend 16 to behave more aggressively. 17 Q. Do low-grade serous carcinomas behave 18 differently from endometrioid, clear cell, and 19 high-grade serous carcinomas? 20 A. They tend to be less aggressive. They 21 all tend to be less aggressive than the 22 high-grade serous carcinomas or other high-grade 23 carcinomas of the ovary. 24 Q. And are they thought to each have 25 different cells of origin?</p>
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<p>1 I asked, "Do they behave differently?" 2 And then you responded, "So the high-grade 3 surface epithelial carcinomas have a more 4 aggressive pathway or presentation. The 5 low-grade surface epithelial carcinomas tend to 6 have a more indolent..." 7 Were you talking about high-grade serous and 8 low-grade serous carcinomas? 9 A. I was talking -- sorry. I was talking 10 about high-grade serous carcinomas, yeah. And we 11 also have sort of undifferentiated carcinomas 12 that are also considered high grade. 13 Q. Okay. And were you talking about 14 low-grade serous carcinomas when you said 15 "low-grade surface"? 16 A. No. So "surface" doesn't really refer 17 to cell type; it's just sort of a -- 18 Q. Right. 19 A. -- an umbrella term for the epithelial 20 carcinoma. 21 Q. Right, which is my point. I just 22 wanted to be clear. When you say "surface" -- 23 A. Yes. 24 Q. -- could you instead use the actual 25 cell type.</p>	<p>1 A. Again, we're not entirely sure where 2 these tumors are arising from, particularly with 3 mucinous carcinomas. I think mucinous carcinomas 4 and there's also a type transitional cell, which 5 is very, very rare, and most of the literature, 6 when it comes to the epi data, don't really 7 discuss transitional cell. 8 But putting that aside, mucinous carcinomas 9 we have, I think, the least amount of data on 10 where they are actually arising from. Clear cell 11 and endometrial carcinomas have an association 12 with endometriosis, but, again, you know, are all 13 cases of endometrioid and clear cell carcinomas, 14 are they all arising from endometriosis? I don't 15 think I can say that. I don't think we know for 16 sure. 17 And serous carcinomas, we talked about the 18 precursor lesions and the fallopian tubes. 19 So there are differences where we think the 20 tumors are arising from, but, again, I don't 21 think we have absolutes where we can definitively 22 say, you know, this particular tumor in this 23 particular woman arised [sic] from this precursor 24 or... 25 Q. Okay. And do you know if the different</p>

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<p>1 histologic subtypes have been associated in the 2 epidemiologic literature with different risk 3 factors?</p> <p>4 A. Yes. Again, I think we touched on some 5 of that before. There is an association with 6 endometrioid and clear cell with endometriosis 7 and obesity.</p> <p>8 Mucinous carcinomas have shown to be 9 associated in some studies with a smoking 10 history.</p> <p>11 High-grade serous carcinomas, it's a little 12 bit harder. We know that BRCA1 and BRCA2 13 patients have an increased risk.</p> <p>14 Q. Now that we're on that topic of 15 genetics, do you know what proportion -- 16 currently, what is believed to be the proportion 17 of ovarian cancers that are caused by germline 18 mutations?</p> <p>19 A. Off the top of my head, I think -- do I 20 have that in my report? But I -- I'm thinking 21 it's 10 to 20 percent, but that's off the top of 22 my head.</p> <p>23 Q. Have you seen any research coming out 24 of Seattle Cancer Care Alliance over the last 10 25 or 15 years that indicates the number could be as</p>	<p>1 Q. -- this is an article by Karen 2 Malmberg, et al., entitled "Serous tubal 3 intraepithelial carcinoma, chronic fallopian tube 4 injury, and serous carcinoma development," and it 5 was in Virchows Archives, March of 2016. 6 MR. TISI: What did you mark this? I'm 7 sorry. 8 MS. AHERN: I marked this one 9. Thank 9 you. No -- yes, 9. 10 MR. TISI: Oh, I'm sorry. 11 MS. AHERN: That's okay. 12 Q. Do you recall if you've ever reviewed 13 this article? 14 A. It's possible. It's certainly possible 15 that I have seen this before in just my daily 16 practice. I don't believe I cited it in any of 17 the references that I can remember, but it's 18 highly possible that I've seen it. 19 Q. Do you see the first page that -- you 20 can just skip if you want, take your time reading 21 it if you'd like, but the authors conclude in 22 their study that there is no correlation with 23 chronic tubal injury or inflammation with the 24 development of STIC lesions or the existence of 25 STIC lesions.</p>
<p>1 high as a quarter of all ovarian cancers being 2 linked to germline mutations?</p> <p>3 A. That would roughly fit with what I just 4 said, 10 to 20 percent. I can't say for sure 5 that I have seen that. I might have. But it 6 fits with what I remember.</p> <p>7 Q. I had asked you earlier if you had 8 reviewed any literature relating to inflammatory 9 conditions and associations with early STIC 10 lesions.</p> <p>11 And you -- and, I'm sorry, I don't want to 12 misstate your response. What was your response 13 to that?</p> <p>14 A. Had I reviewed literature? Yes, I've 15 seen literature.</p> <p>16 Q. Okay. 17 (Article entitled "Serous tubal 18 intraepithelial carcinoma, chronic 19 fallopian tube injury, and serous carcinoma 20 development" marked Exhibit 9.)</p> <p>21 BY MS. AHERN: 22 Q. I'm handing you what's been marked as 23 Exhibit 9 to your deposition. And this is -- 24 MS. AHERN: I don't know if anyone else 25 wants one.</p>	<p>1 Do you see that? 2 A. No. Can you -- I'm sorry, can you 3 point to me -- 4 Q. Oh, sure. 5 A. -- where? 6 Q. Do you see the abstract, if you carry 7 it over to the second column? 8 A. Mm-hmm. Yes. 9 Q. It says, "STIC and invasive cancer were 10 seen more often in the older patients than in the 11 younger patients"?</p> <p>12 A. Mm-hmm. 13 Q. This study is -- small study, no 14 correlation with chronic tubal injury or 15 inflammation was identified. 16 A. Yes, with the caveat -- that was a 17 conclusion with the caveat that it was a small 18 study. 19 Q. Have you -- as a gynecologic 20 pathologist or a pathologist who has subspecialty 21 training in gynecologic malignancies, how often 22 do you see chronic -- or evidence of chronic 23 inflammation surrounding STIC lesions? 24 Or strike that. How often do you see STIC 25 lesions?</p>

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<p>1        A. On -- certainly, I can't give you a      2        number. I've certainly made the diagnosis and      3        see it -- I can't give you a number of how many      4        times.</p> <p>5        Q. Have you ever been involved in a study      6        looking specifically at STIC lesions and      7        high-grade serous carcinomas?</p> <p>8        A. I have not been involved in a study,      9        no.</p> <p>10      Q. Have you ever seen evidence of chronic      11     inflammation with a STIC lesion?</p> <p>12      A. Off the top of my head, I am not sure.      13     It's possible, but I can't really answer that off      14     the top of my head.</p> <p>15      Q. How often do you see chronic      16     inflammation in the fallopian tubes associated      17     with high-grade serous carcinoma?</p> <p>18      A. You can certainly see it, but it sort      19     of goes along with the discussion that we had      20     before. You can see chronic inflammation within      21     the tumor, as well.</p> <p>22      And so I think, you know, the literature      23     is -- the research is ongoing as to, you know...</p> <p>24      Q. So once the tumor -- once there's a lot      25     of tumor burden in the abdominal cavity, it's</p>	<p>1        looks --</p> <p>2        MR. ROTMAN: Just so the record is      3        clear, when you said "this," do you want to      4        identify it?</p> <p>5        A. Sorry. The fourth edition belongs to a      6        colleague. The fifth edition is my own.</p> <p>7        MS. AHERN: Okay. We'll get to that      8        one. I'll mark that next.</p> <p>9        Q. There is a photocopy here, "Blaustein's      10      Pathology of the Female Genital Tract, Fourth      11      Edition," Pages 300 and -- well, Page 376,      12      Page 539, Page 540, 648, 1216, 1217, 1218.</p> <p>13      Is this a copy -- are these copies that you      14      made?</p> <p>15      A. Yes.</p> <p>16      Q. Okay.</p> <p>17      MR. TISI: Do you have a stapler?      18      Otherwise I'll get one.</p> <p>19      MS. AHERN: No, I don't have one.</p> <p>20      MR. TISI: No, I'll go get one.</p> <p>21      BY MS. AHERN:</p> <p>22      Q. Can you tell me why you made those      23      copies?</p> <p>24      A. I made them because it was easier than      25      lugging around a whole textbook. That's why I</p>	<p>1        difficult to tell where the inflammation is      2        coming from or what started it; is that correct?</p> <p>3        A. Well, if there's chronic inflammation      4        in the tumor, it's likely the tumor has something      5        to do with the chronic inflammation.</p> <p>6        But, again, you know, as we talked about      7        before, I think sometimes it is difficult to      8        tell.</p> <p>9        MS. AHERN: Okay. Housekeeping matters      10      before I forget.</p> <p>11      Let me go ahead somehow and mark --      12      let's mark -- we can remove this later --      13      "Blaustein's Pathology of the Female Genital      14      Tract," Fourth Edition, as Exhibit 10 to your      15      deposition.</p> <p>16      ("Blaustein's Pathology of the      17      Female Genital Tract," Fourth Edition,      18      marked Exhibit 10.)</p> <p>19      BY MS. AHERN:</p> <p>20      Q. And, Doctor, you brought this textbook      21      with you today.</p> <p>22      Is this your textbook?</p> <p>23      A. That particular copy is not. That's my      24      coworker's copy. This copy is mine (indicating).</p> <p>25      Q. Okay. And inside this, you have what</p> <p>1        Xeroxed them. But --</p> <p>2        Q. You had to bring it anyway.</p> <p>3        Sorry. Go ahead.</p> <p>4        A. But the particular pages that I copied      5        are ones that talk about granulomatous reactions      6        to talc in the female reproductive system.</p> <p>7        Oh, sorry. Okay.</p> <p>8        MS. AHERN: Okay. We'll go ahead and      9        mark those copies as Exhibit 10 to your      10      deposition.</p> <p>11      Q. And just to confirm --</p> <p>12      MS. AHERN: Sorry. Are we on 10 or 11?</p> <p>13      We're on 11. Thank you.</p> <p>14      Q. As a --</p> <p>15      MR. TISI: Is this the next one?</p> <p>16      MS. AHERN: Yeah. Hold on. I'm going      17      to clarify it.</p> <p>18      Q. So this photocopy that you made from      19      Blaustein's came from the fourth edition?</p> <p>20      A. Correct.</p> <p>21      Q. The textbook that we have here marked      22      as Exhibit 10.</p> <p>23      A. (Witness nodded.)</p> <p>24      Q. Okay. So Exhibit 11 are photocopies of      25      specific pages from Exhibit 10, which is</p>

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<p>1 Blaustein's Pathology of the Female Genital      2 Tract, Fourth Edition.      3 (Excerpt from "Blaustein's      4 Pathology of the Female Genital Tract,"      5 Fourth Edition, marked Exhibit 11.)      6 BY MS. AHERN:      7 Q. Okay. And can you tell me, with      8 Exhibit 11, the specific information that you      9 found relevant to your opinions in this case?      10 A. Okay. So on Page --      11 MR. ROTMAN: You marked the copy as      12 Exhibit 11 and the book as Exhibit 10?      13 MS. AHERN: Mm-hmm.      14 MR. ROTMAN: Okay.      15 A. Okay. You have to bear with me,      16 because I don't have any highlights or anything,      17 so I have to find it.      18 So Page 376, right down -- okay. The last      19 paragraph under "Zanko Granulomatous      20 Inflammation," it says, "Rarely, talc or another      21 foreign substance may elicit a foreign-body      22 reaction in the endometrium. Talc may be      23 introduced into the endometrial cavity by      24 instruments contaminated with talcum powder or by      25 gloves during a pelvic examination. Patients may</p>	<p>1 evidence, and it shows that talc can cause      2 granulomatous or chronic inflammation in the      3 female reproductive tract.      4 Q. And how is uterine cancer related to,      5 for instance, high-grade serous carcinoma of the      6 ovary?      7 A. Again, this is just evidence that talc      8 can cause chronic inflammation and granulomas in      9 the endometrium, which I think is another piece      10 of evidence that talc can cause chronic      11 inflammation and granulomatous inflammation in      12 the female reproductive tract.      13 Q. Doctor, shouldn't talc -- based on the      14 literature that we have available to us over the      15 last 50 years, shouldn't talc induce that      16 response in any tissue that it's found in?      17 A. Well, again, different tissues will      18 respond in different ways, but I think it also      19 depends -- well, I'll just...      20 Q. Well, as a pathologist --      21 MR. ROTMAN: Wait. Wait. Are you      22 done?      23 MS. AHERN: Are you done?      24 THE WITNESS: I think so.      25 Q. Okay. So as an anatomic pathologist</p>
<p style="text-align: center;">Page 99</p> <p>1 be asymptomatic or may have menorrhagia.      2 Microscopically, the extent of the granulomatous      3 inflammatory reaction depends on the quantity of      4 talc inoculated. The infiltrate is characterized      5 by histiocytes and foreign-body multinucleated      6 giant cells surrounding the talc crystals, along      7 with lymphocytes and plasma cells. The crystals      8 appear as refractile, birefringent, needle-like,      9 or fan-shaped splinters in polarizing light."      10 Then on Page 530 --      11 Q. Sorry. Let me just -- let's take this      12 in order.      13 So what about that particular passage      14 informs your causation opinions regarding talc      15 and ovarian cancer, if at all?      16 A. So it is evidence that talc causes      17 foreign-body giant cell reaction and chronic      18 inflammation in the endometrium.      19 Q. And that is the uterine tissue;      20 correct?      21 A. That's the lining of the uterus,      22 correct.      23 Q. And how does that inform your opinions      24 regarding the development of ovarian cancer?      25 A. Well, I thought, again, it's a piece of</p>	<p style="text-align: center;">Page 101</p> <p>1 who knows something about granulomatous      2 reactions, shouldn't a foreign body produce a      3 foreign-body reaction in any tissue that it's      4 found in?      5 A. Not -- no, not always. Sometimes you      6 will have a foreign body that won't cause a      7 foreign-body giant cell reaction. It depends      8 on -- it depends on the particle, the foreign      9 body, the tissue it's in. You don't always see      10 that. And also the timing, when you're looking      11 at it, versus how long it's been there.      12 Q. Well, the timing is just more or less      13 when you observed it, not whether it occurred;      14 correct?      15 MR. ROTMAN: Objection.      16 A. So it's hard to know whether or not it      17 occurred -- if it had been there for a long time      18 and you're looking years, you know, in -- years      19 after it's been there, if you don't see a      20 granulomatous or chronic inflammation, that's not      21 evidence that it never occurred; it's just you're      22 not seeing it at that moment.      23 Q. Do you know of any -- any foreign      24 bodies that generate tissue-specific reactions?      25 A. Well, we -- I mean, we certainly have</p>

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<p>1 evidence with, say, viruses and bacteria that      2 respond differently -- certain tissues will      3 respond differently to different infections.      4 For esophageal cancer, there's some      5 literature to suggest that very hot liquids      6 increase your risk of esophageal cancer. So,      7 yes, certain tissues will respond differently to      8 different material.</p> <p>9 Q. So my question was -- it might be just      10 a little simpler to think of just this      11 question -- do you know of any foreign bodies --      12 I'm not talking about viruses and bacteria which      13 cause immune responses -- but foreign bodies that      14 generate a tissue-specific foreign-body reaction?</p> <p>15 A. Well, it's sort of semantics. I mean,      16 viruses and bacteria -- that's why I answered the      17 way I did -- are foreign to -- and, certainly,      18 foreign bodies can elicit immune response.      19 That's why you see granulomatous reactions and      20 chronic inflammation.</p> <p>21 So I guess I'm not -- I think I answered the      22 question.</p> <p>23 Q. Pathologists distinguish the different      24 types of granulomatous inflammation based on the      25 cause of the inflammation; correct?</p>	<p>1 granulomas, which are caused by talc and      2 cornstarch and certain other inert-type      3 materials; correct?</p> <p>4 MR. ROTMAN: Objection.</p> <p>5 A. Again, you can have inflammation --      6 granulomatous inflammation due to infection, you      7 can have granulomatous infection -- response due      8 to foreign bodies, and you can have granulomas in      9 certain diseases, like sarcoidosis or Crohn's      10 disease.</p> <p>11 So in that respect, yes, we're categorizing      12 granulomas, but on a daily basis, other than that      13 type of breakdown, we're not subcategorizing      14 granulomas.</p> <p>15 Q. But you are aware of the literature      16 that actually characterizes the different types      17 of granulomas and the types of cells that are      18 involved in the formation of those granulomas;      19 correct?</p> <p>20 A. As far as foreign-body giant cells and      21 multinucleated giant cells and inflammatory      22 versus foreign body, yes.</p> <p>23 Q. So, you know, a granuloma caused by      24 tuberculosis is going to be very different from a      25 granuloma caused by talc; correct?</p>
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<p>1 A. We look for -- if we see granulomatous      2 inflammation in tissue, we certainly look for a      3 potential cause. We want to rule out infection,      4 so if we see granulomas, we'll routinely do      5 special stains to rule out infection. Like we'll      6 do an acid-fast Bacillus stain for microbacteria.      7 We'll do fungal stains to rule out a fungal      8 infection that causes inflammation.</p> <p>9 And then, of course, if we have -- if those      10 are negative and we're trying to figure out if      11 there's a foreign body within a granuloma, we can      12 use polarized light to try to find the foreign      13 body to identify it as a foreign-body giant cell      14 reaction.</p> <p>15 But often you do have granulomatous      16 inflammation and you won't find fungi -- fungal      17 lesions -- fungal bodies or bacteria or      18 birefringent particles on them, so you don't      19 necessarily know why you have a granulomatous      20 inflammation.</p> <p>21 Q. Pathologists categorize granulomatous      22 inflammation, don't they? They categorize it in      23 terms of the different types of immune granulomas      24 and the etiologic agents for those granulomas,      25 and over here somewhere are the foreign-body</p>	<p>1 MR. ROTMAN: Objection.</p> <p>2 A. I would say not necessarily. In      3 microbacterial infections, you can have necrosis      4 within granulomas, but that doesn't mean that      5 you're not necessarily going to see necrosis in a      6 foreign-body granuloma.</p> <p>7 Q. How often have you seen necrosis      8 associated with a foreign-body granuloma?</p> <p>9 A. I'd say more commonly you see      10 necrotizing or necrotic granulomas in infectious      11 granulomas.</p> <p>12 Q. There are different types of      13 macrophages that are involved, too, in      14 foreign-body granulomas and in immune granulomas;      15 correct?</p> <p>16 A. As far as macrophages themselves and      17 multinucleated giant cells that can form      18 granulomas.</p> <p>19 Q. There are different types, different      20 subtypes of macrophages that are involved in --</p> <p>21 A. Yes.</p> <p>22 Q. -- those activities; correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. So there are differences between      25 a foreign-body granuloma and an immune granuloma?</p>

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<p>1       A. There can be. 2       Q. Well, there are, aren't there? I mean, 3       there are papers that characterize these. 4       A. Yes, but I'm -- yes. In the 5       literature, yes. And -- but are we necessarily 6       categorizing them when we're looking at a 7       particular patient? We're looking for the cause 8       of the granuloma, but we're not necessarily 9       subcategorizing, is my point. 10      Q. Understood. 11      Oh, I'm sorry. We were talking about the 12     pages that you copied from Blaustein's. 13      What was the second page in that photocopy, 14     Exhibit 11? 15      A. Okay. So Page 539. 16      Q. What was it on 539 that's relevant to 17     your opinions in this case? 18      A. Okay. I think it starts at the very 19     bottom. I think it carries into Page 540, where 20     it starts talking about foreign-body reactions in 21     the -- this is diseases of the fallopian tube. 22      So it starts, "Foreign material may be 23     introduced into the tube in the course of 24     gynecological investigation, especially 25     hysterosalpingography, lubricant jelly, mineral</p>	<p>1       cancer, which is sort of the plausibility arm of 2       the Bradford Hill. I think it's compelling 3       evidence that we see that you can get 4       granulomatous inflammation and some of these 5       sections have mentioned lymphocytes and plasma 6       cells in the tissue. I mean, I think it's a 7       further piece of evidence that talc can cause 8       these -- this type of inflammation in female 9       reproductive market. 10      Q. How often have you, in your career, 11     seen a talc granuloma in gynecologic specimens? 12      A. We don't routinely do -- perform 13     polarized light microscopy on ovarian tumors, 14     partly because you really need electron 15     microscopy. You can -- with polarized light 16     microscopy, you can tell that there's a foreign 17     substance there, but that's pretty much as far as 18     you can -- you can get. You need more testing to 19     be able to determine what type of particle it is, 20     usually. So we don't, in daily practice, 21     routinely use polarized light microscopy. 22      Now, it's entirely possible that, you know, 23     in the course of my career, I've come across 24     chronic inflammation or granulomas in an ovarian 25     tumor that could have been due to talc that I</p>
<p style="text-align: center;">Page 107</p> <p>1       oil, and starch and talc powder may cause lipid 2       or granulomatous salpingitis. Talc may cause 3       mucosal or serosal granulomas. Examination of 4       all granulomas or foreign-body reactions under 5       polarized light is useful in the recognition of 6       these processes." 7       So, again, I'm just referencing the fact 8       that talc can cause granulomatous reaction in the 9       fallopian tube. 10      Q. So another tissue that's exposed to 11     talc forms the typical type of foreign-body 12     response? 13      A. That can form a granulomatous reaction. 14      Q. Okay. And does that in any way inform 15     your opinions on causation, other than 16     granulomatous reactions occur? 17      A. Well, so, again, it's another piece of 18     evidence that talc can cause a granulomatous 19     reaction within the female reproductive tract. 20      Now, the fallopian tube, we know some -- has 21     been indicated as a precursor site for certain 22     high-grade serous carcinomas, so I think it's 23     relevant. 24      But, again, you know, we're talking about 25     mechanisms that talc may eventually cause ovarian</p>	<p style="text-align: center;">Page 109</p> <p>1       didn't polarize so I didn't see particles, I 2       guess. 3       Q. So let me back up and just ask you: 4       How often in your career have you seen 5       foreign-body granulomas? Regardless of whether 6       you've identified the particle in the granuloma, 7       how often have you seen foreign-body granulomas 8       in gynecologic specimens? Not just tumors, but 9       any gynecologic specimens you've reviewed. 10      A. No, I understand. 11      Q. Okay. 12      A. You can certainly see granulomas -- how 13     often, I can't give you a number; that would just 14     be wildly guessing -- but you can see granulomas 15     in the endometrium. You can see them in 16     different types of tumor. 17      Sometimes it's -- you'll see granulomas, but 18     you won't see a particle, so you don't know for 19     sure if it's a foreign-body granuloma; you just 20     see the granuloma because you're not using 21     polarized light microscopy on it. 22      MR. KLATT: Object. Nonresponsive. 23      MS. AHERN: Same. 24      Q. So how often, though, in your career -- 25     you can give me an estimate -- have you seen</p>

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<p>1 foreign-body granulomas in gynecologic specimens?</p> <p>2 MR. ROTMAN: Objection.</p> <p>3 Q. I'm not talking about immune</p> <p>4 granulomas, but just foreign-body granulomas.</p> <p>5 We'll start there.</p> <p>6 MR. ROTMAN: Objection. You've asked</p> <p>7 that question. She's answered it.</p> <p>8 A. So, again, I've seen granulomas in my</p> <p>9 career in the female reproductive tract, but I</p> <p>10 don't -- pathologists don't routinely use</p> <p>11 polarized light microscopy in that instance to</p> <p>12 look for foreign bodies.</p> <p>13 Q. Okay. So are you done?</p> <p>14 MR. ROTMAN: Can we take a break?</p> <p>15 MS. AHERN: Not just yet. Let me</p> <p>16 finish this line of questioning and then we can</p> <p>17 take a break. Because we may want to -- what</p> <p>18 time is it?</p> <p>19 MR. ROTMAN: It's been an hour.</p> <p>20 MS. AHERN: 11:30. If we go a little</p> <p>21 bit longer, we can break for lunch if you want.</p> <p>22 MR. ROTMAN: I just want to take a</p> <p>23 break in the next few minutes.</p> <p>24 MS. AHERN: Sure.</p> <p>25</p>	<p>1 foreign body, you're not necessarily going to be</p> <p>2 able to say whether or not it's a foreign-body</p> <p>3 granuloma with absolute certainty unless you're</p> <p>4 looking under polarized light microscopy. And</p> <p>5 even then, you might not see it under polarized</p> <p>6 light microscopy, because it depends on the</p> <p>7 section of the tissue you're looking at and --</p> <p>8 Q. Okay. Thank you.</p> <p>9 And if you see a foreign-body response in</p> <p>10 tissue, do you then go one step further and</p> <p>11 polarize to see if you can identify whether</p> <p>12 that's got a foreign body in it?</p> <p>13 A. It certainly depends on the situation.</p> <p>14 So, for example, in cases where there's been</p> <p>15 a surgery and they've taken out more tissue after</p> <p>16 surgery, you might be looking for polarizable</p> <p>17 foreign body. Often, you can see a suture on</p> <p>18 light microscopy. But, yeah, we do -- depending</p> <p>19 on the situation, we will use polarized light</p> <p>20 microscopy to find foreign bodies.</p> <p>21 MR. ROTMAN: Okay.</p> <p>22 Q. How often do you polarize specimens</p> <p>23 where you've found a foreign-body response? How</p> <p>24 often do you do that?</p> <p>25 A. I think -- I think I tried to come up</p>
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<p>1 BY MS. AHERN:</p> <p>2 Q. Doctor, are you able, as a -- as a</p> <p>3 pathologist, under regular light microscopy to</p> <p>4 identify a foreign-body granuloma? Not the</p> <p>5 content, just the foreign-body granuloma.</p> <p>6 A. I would say it depends on the specific</p> <p>7 granuloma. Sometimes, for example, in epidermal</p> <p>8 inclusion cysts, you can see the keratin under</p> <p>9 light microscopy that's causing the reaction, but</p> <p>10 you don't always -- you won't always necessarily</p> <p>11 see a particle. They're very small. And unless</p> <p>12 you're looking specifically for polarizable</p> <p>13 birefringent particles, you're not going to see</p> <p>14 it just with regular light microscopy.</p> <p>15 Q. So my question wasn't -- and I thought</p> <p>16 I was specific -- my question wasn't whether or</p> <p>17 not you could see the particle; my question was:</p> <p>18 You should be able to see the foreign-body</p> <p>19 response in terms of multinucleated giant cells.</p> <p>20 Do you -- can you see that under regular</p> <p>21 light microscopy?</p> <p>22 A. Well, so you're categorizing it as a</p> <p>23 foreign-body granuloma. What I'm saying is you</p> <p>24 can see granulomas, of course, under light</p> <p>25 microscopy. But if you're not looking for a</p>	<p>1 with an estimate. I think I have it in my</p> <p>2 report, actually, in the beginning.</p> <p>3 Yes. So I estimated that I use polarized</p> <p>4 light microscopy for this purpose, which is</p> <p>5 identifying foreign material to explain an</p> <p>6 inflammatory reaction, I estimated about twice a</p> <p>7 month. It's an estimate.</p> <p>8 And I -- well, that was -- actually, I was</p> <p>9 referring to calcium oxalate crystals in breast</p> <p>10 biopsies. That's different. So it's not</p> <p>11 uncommon, let's put it that way, but I can't</p> <p>12 really give you a -- an estimate.</p> <p>13 Q. What was the estimate for breast</p> <p>14 tissue?</p> <p>15 A. I think it was twice a month, is what I</p> <p>16 said.</p> <p>17 Q. So compared to looking for calcium</p> <p>18 crystals in breast tissue twice a month, how</p> <p>19 often in gynecologic specimens do you look for</p> <p>20 foreign bodies?</p> <p>21 A. I would say slightly less than that.</p> <p>22 Q. Maybe once a month, maybe less than</p> <p>23 that?</p> <p>24 A. Once a month is probably a good</p> <p>25 estimate, I guess.</p>

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<p>1 Q. Do you know, based on your review of 2 the epidemiologic literature, what proportion of 3 women are said to use talc? 4 A. I believe I've seen in some of the 5 literature -- it depends on the population, I 6 think. I think I saw -- well, again, I'd have to 7 pull out the papers to be absolutely certain, but 8 I remember there was a reference to 9 African-American women, about 50 percent of them 10 using talc. 11 Q. Would you say that in 50 percent of the 12 gynecologic specimens you review, you find 13 foreign-body granulomas or granulomas? 14 A. Well, I wouldn't necessarily expect -- 15 I wouldn't expect to, just because, you know, 16 again, we're looking at an ovarian tumor at a 17 very particular point in time. 18 How many granulomas -- how much talc is 19 getting to the ovary, we don't -- we don't know 20 how much talc is getting to the ovary. We know 21 it's been found there, we know it can get there, 22 but we don't know with how much use, how much is 23 actually getting there. 24 So we wouldn't necessarily find a lot of 25 granulomas in ovarian tissue of women that use</p>	<p>1 I mean, it's not -- it's not frequent that 2 you're going to find foreign-body giant cell 3 reactions in tissue, but, again, it doesn't mean 4 that they weren't there. Maybe -- 5 Q. And this is based just on your 6 experience. I know that -- I don't want you to 7 guess about what might have been there -- 8 A. Yeah, I'm -- 9 Q. -- but based on your experience as a 10 practicing pathologist. 11 A. It would just be a pure guess at this 12 point. I couldn't give you an accurate number. 13 Q. Do you see foreign-body reactions in 14 50 percent of the gynecologic specimens or cases 15 that you review? 16 MR. ROTMAN: Objection. 17 A. I would say it's less than 50 percent. 18 Q. Is it less than 25? 19 A. I would say less than 25. 20 Q. Less than ten? 21 A. Probably less than ten. 22 Q. Less than five? 23 A. That's where I'm not exactly sure. 24 Q. Okay. 25 MS. AHERN: All right. We can go ahead</p>
<p>1 it, because we don't know exactly how much is 2 getting there or we don't know how long those 3 granulomas are there once the tissue is in the 4 ovary. 5 I mean, 20 years later, when you're looking 6 at the -- at the ovary for a talc particle that's 7 been there, we don't know if the granuloma would 8 still be there or the chronic inflammation would 9 still be there. 10 Q. And my question wasn't specific to 11 ovarian tissue; it was just gynecologic 12 specimens. 13 Because you review more than ovarian tissues 14 when you're looking at gynecologic samples; 15 correct? 16 A. Yes. 17 Q. So looking at all of your gynecologic 18 specimens, your vaginal, vulvar, endometrial, 19 tubal, ovarian, I guess omentum might fall in 20 there, how often do you identify foreign bodies 21 or foreign-body granulomas? 22 A. I would have to be -- a completely 23 ballpark guess, but, I don't know, maybe every -- 24 I'm really trying to figure out a somewhat 25 ballpark figure. It's tough.</p>	<p>1 and take a break. Thank you. 2 THE VIDEOGRAPHER: Here ends Media 2. 3 Off the record, 11:44 a.m. 4 (A recess was taken.) 5 THE VIDEOGRAPHER: Here begins Media 6 No. 3 in today's deposition of Sarah Kane, M.D. 7 Back on the record, 12:02 p.m. 8 BY MS. AHERN: 9 Q. All right. Doctor, can we go ahead and 10 keep moving through that photocopy, Exhibit 11. 11 Can you tell me what the next page was? 12 A. Okay. We just read from Page 540, I 13 believe, so the next one is Page 648. 14 Q. Okay. And tell me what on 648 caught 15 your eye. 16 A. Okay. It's the first paragraph under 17 "Noninfectious Granulomatous Peritonitis." So it 18 says, "Foreign material typically recognizable on 19 histologic examination can elicit a granulomatous 20 reaction on the peritoneum. Starch granulomas 21 from surgical gloves, douche fluid, and 22 lubricants typically incite a granulomatous and 23 fibrosing peritonitis. In occasional cases, the 24 inflammatory reaction may be a tuberculoid type 25 with KCS necrosis. The periodic acid shift (PAS)</p>

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<p>1 positive starch granules exhibit the 2 characteristic Maltese cross configuration" -- 3 THE COURT REPORTER: I'm sorry, you're 4 reading too fast. 5 THE WITNESS: I'm sorry. 6 A. "The periodic acid shift (PAS) positive 7 starch granules exhibits a characteristic Maltese 8 cross configuration under polarized light. Talc 9 was once an important cause of granulomatous and 10 fibrosing peritonitis because of its use as a 11 lubricant on surgical gloves and talc-induced 12 peritonitis has been described more recently in 13 drug abusers." I think that's kind of where it 14 stops. 15 Q. Okay. And how does that passage that 16 you just read inform your opinions in this case? 17 A. Well, again, it's just another -- 18 similar to the last pieces, this is the 19 peritoneum, so this is outside of the fallopian 20 tube. Once particles are outside of the 21 fallopian tube, they are in the peritoneum. 22 That's where the ovary is. And so it's 23 discussing foreign-body granulomatous reactions 24 in the peritoneum. 25 Q. And this question -- this passage that</p>	<p>1 head. 2 Q. And when you say "they" were looking 3 at, are you talking -- who are you talking about? 4 A. When the -- when the regulatory -- if I 5 recall -- did I put that in my report? -- they 6 removed -- I know that they removed starch from 7 surgical gloves because it was causing an 8 inflammatory reaction. 9 And they had started using starch more 10 commonly because talc had been removed from 11 surgical gloves for also causing inflammatory 12 reactions. 13 Q. And talc particles and cornstarch 14 particles cause the same foreign-body reaction in 15 the peritoneum and fibrosis; correct? 16 A. Well, again, they can cause a 17 granulomatous reaction, but they're 18 bioabsorbable, so it's not going to be -- you 19 know, when we're talking about talc, we're 20 talking about the talc in surgical gloves. And, 21 you know, talc is not bioabsorbable and it will 22 stay in the peritoneum longer than starch, which 23 is bioabsorbable. So it will -- the inflammation 24 will likely resolve more quickly. It's a 25 different -- it's a different type of reaction</p>
<p style="text-align: center;">Page 119</p> <p>1 you just read also mentions that starch granules 2 from surgical gloves -- 3 A. Yes. 4 Q. -- cause granulomatous and fibrosing 5 peritonitis, which is the same that they mention 6 talc use to. 7 Would you say that starch granules, then, 8 have the capacity to cause chronic inflammation 9 that can lead to cancer? 10 A. Starch can cause inflammatory 11 reactions, but it's a -- very different, in that 12 it's bioabsorbable, and so the particles are 13 absorbed in the body. And the literature hasn't 14 supported a link between starch and ovarian 15 cancer. 16 Q. How many studies have evaluated the 17 association between starch and ovarian cancer? 18 A. I couldn't say, off the top of my head, 19 how many. But I know, you know, they looked at 20 starch when they were evaluating whether or not 21 to remove it from surgical gloves, and they ended 22 up deciding to remove it from surgical gloves. 23 And I -- I think at that point they had done 24 a literature search. I don't think there was -- 25 I don't know how many studies off the top of my</p>	<p style="text-align: center;">Page 121</p> <p>1 because it's bioabsorbable. 2 Q. Well, they both cause granulomas; 3 right? 4 A. Mm-hmm. 5 Q. And they both cause fibrosis; correct? 6 A. They can cause fibrosis. 7 Q. Does the biodurability of the causative 8 agent determine how long fibrosis exists? 9 A. Well, the fibrosis is thought to arise 10 from the inflammatory process. And since -- I 11 don't know how much data is really there except 12 to say that starch is bioabsorbable and talc is 13 not. So talc is going to be available for an 14 inflammatory response more than a starch particle 15 will. 16 Q. Is the purpose of a foreign-body 17 granuloma to essentially wall off an irritant, a 18 foreign body, from the rest of the tissue to 19 prevent damage? 20 A. That can be one reason. 21 Another reason is if the particle is large 22 enough and one macrophage can't handle it because 23 of its size, it will sort of recruit more 24 macrophages to the area to try to digest the 25 foreign material, which is not going to -- they</p>

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<p>1 won't be able to digest the talc particle. 2 Q. If they can't digest the particle, 3 these macrophages will fuse to form a 4 multinucleated giant cell and surround the 5 particle to basically encapsulate it and prevent 6 it from harming the surrounding tissue; correct? 7 A. It's possible that they would, yes, 8 they would recruit more macrophages and 9 potentially do that. 10 Q. Isn't that the purpose of a 11 foreign-body granuloma? 12 A. So, again, you can get well-formed -- 13 you can get well-formed encapsulated granulomas. 14 You can also get sort of poorly formed granulomas 15 that are -- when more macrophages have been 16 recruited to that site. 17 You can get a -- you can get a histiocytic 18 reaction that isn't a well-formed granuloma in 19 the sense that you're talking about, where it's 20 kind of walling off the foreign body. You can 21 get histiocytic reactions that aren't as well 22 formed like that. 23 Q. But we're just talking about the actual 24 granuloma itself, those particles that do result 25 in a well-formed granuloma.</p>	<p>1 macrophages are continuously recruited to 2 foreign-body granulomas? 3 A. I know that I've read it in the course 4 of my daily practice. I can search at some point 5 for it, but I know that that's the case, because 6 I know that macrophages, again, have a certain 7 lifespan. 8 But, you know, again, the inflammatory 9 response, we also don't know how long that 10 inflammatory response is going to be there for 11 sure. Is it possible that at some point the 12 granuloma resolves and you get some fibrosis and 13 the talc particle or whatever particle is there 14 remains? I think that's possible and likely, in 15 fact, because you do see resolution of granulomas 16 with fibrosis. 17 Q. Is fibrosis associated with the 18 development of ovarian cancer? 19 A. There hasn't -- there hasn't been a 20 lot -- again, the causes of ovarian cancer are 21 sort of -- the literature and the research is 22 still bearing all of it out, but from what I know 23 of the literature, I don't think that they found 24 fibrosis itself being an increased risk factor 25 for ovarian cancer.</p>
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<p>1 Once that granuloma has formed, it can 2 persist for many years, can't it, without 3 damaging the surrounding tissue? 4 MR. ROTMAN: Objection. 5 A. I think it would depend. Macrophages 6 have a certain lifespan, so it's going to be 7 constantly recruiting different macrophages to 8 that site. 9 So I don't think we can say for certain that 10 the -- in fact, I think the body is still 11 reacting to that foreign body if it's still 12 recruiting new macrophages in. 13 Q. Do you know that for a fact based on 14 your reading of the literature of granulomas, 15 that that's the mechanism behind a foreign-body 16 granuloma, as opposed to an immune granuloma? 17 A. What I'm saying is -- is that 18 macrophages have a certain shelf life, and so 19 they will constantly recruit new macrophages to 20 that area. 21 Now, whether or not there's an exposure in 22 that particle while it's in that process, I don't 23 think we can definitively say. 24 Q. Can you cite to any papers that support 25 your understanding of that process whereby</p>	<p>1 Q. Is fibrosis associated with chronic 2 inflammation? 3 A. It can be, yeah. Chronic inflammation 4 can lead to fibrosis. 5 Q. Do you know of any literature that has 6 linked talc granulomas introduced into the body 7 through the use of talc-dusted surgical gloves 8 with any sort of cancer? 9 A. So we know that talc can -- there are 10 studies that have shown talc in the ovaries, and 11 we know that chronic inflammation has been 12 implicated in cancer. 13 So if talc can reach the ovaries -- and we 14 also have evidence that talc causes chronic 15 inflammation. So if talc reaches the ovary, I 16 think it's a plausible mechanism for talc from 17 surgical gloves to cause an inflammatory reaction 18 and lead to cancer. I think that's plausible. 19 And, again, that's the plausibility arm of 20 it. You know, that's a piece of the general 21 causation opinion, but, you know, they're still 22 piecing together a lot of the etiology of ovarian 23 cancer. 24 Q. Then why -- 25 MR. KLATT: Objection, nonresponsive.</p>

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<p>1           MS. AHERN: Nonresponsive, yeah.      2           Q. Doctor, why are you so sure, then, that      3        talc causes ovarian cancer?      4           A. It's --      5           MR. ROTMAN: Objection.      6           A. So I can lay out to you my methodology.      7        It's in the report. I did very in-depth,      8        extensive review of the literature, which      9        included the epi studies, animal studies, and      10      biologic studies.      11      And I think -- well, I know that the epi      12     studies have been very consistent with the      13     increased risk associated with talcum powder      14     product usage -- I'm talking about talcum powder      15     product, what's in the bottle -- and perineal      16     talc application with ovarian cancer.      17      And I think if you're looking at -- if you      18     go through the methodology that I used and you're      19     looking at the Bradford Hill analysis, which I've      20     laid out in the report, I've come to the      21     professional -- you know, my professional      22     judgment is that the talcum powder products --      23     weighing everything, that talcum powder products      24     cause ovarian cancer.      25      And I know -- and, interestingly, about</p>	<p>1           MS. AHERN: No. We're going back to      2        this question.      3           MR. ROTMAN: Okay. That's fine.      4           So you're asking her again a question      5        that she previously answered.      6           MR. KLATT: No --      7           MS. AHERN: I'm interested in --      8           MR. KLATT: -- a question she didn't      9        answer.      10      MS. AHERN: -- the question she didn't      11     answer first.      12      BY MS. AHERN:      13      Q. Which is: "Do you know of any      14     literature that has linked talc granulomas      15     introduced into the body through the use of      16     talc-dusted surgical gloves with any sort of      17     cancer?"      18      Do you know or not know of any literature      19     that supports that?      20      A. Well, first of all, I think we're      21     talking about -- you're talking about surgical      22     glove talc, right, which is pharmaceutical-grade      23     talc, which is different from the talcum powder      24     product that I'm opining about.      25      And we know that these talc particles can</p>
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<p>1        three weeks after I wrote my report, there was      2        the Health Canada report that, in reading their      3        methodology and the literature that they      4        reviewed, was very similar to what I reviewed and      5        my methodology. And they came to the same      6        conclusion.      7           MR. KLATT: Objection.      8           MS. AHERN: Objection. Nonresponsive.      9           Q. Doctor, my question was: Do you know      10      of any literature that has linked -- sorry.      11      My first question we're going to go back to      12      now is: Do you know of any literature that has      13      linked talc granulomas introduced into the body      14      through the use of talc-dusted surgical gloves to      15      any sort of cancer?      16           MR. ROTMAN: Objection.      17           MS. AHERN: What's the objection?      18           MR. ROTMAN: Your question was --      19           MS. AHERN: I'm reading it.      20           MR. ROTMAN: -- why are you so certain.      21           MS. AHERN: Well, I just told you we're      22      going back to this question.      23           MR. ROTMAN: Okay. So you're asking --      24      you're not saying that she didn't -- you're not      25      repeating your former question?</p>	<p>1        get to the ovary and we know that talc can cause      2        chronic inflammation.      3           Q. Doctor, first question about your      4        answer is: What makes you think that cosmetic      5        talc used in Johnson &amp; Johnson baby powder is not      6        pharmaceutical-grade talc?      7           A. I'm talking about the product, the      8        ultimate product.      9           Q. Johnson's baby powder; correct?      10          A. Whatever is in the bottle.      11          Q. You're saying that's not      12        pharmaceutical-grade talc?      13          A. Whatever is in the bottle.      14          Q. Okay.      15          A. So --      16          Q. What is your -- what is your      17        understanding of what pharmaceutical-grade talc      18        is and how is that different from what's in      19        Johnson's baby powder?      20          A. So I didn't opine on the constituents      21        of the talcum powder that -- the baby product --      22        talcum powder products, the Johnson &amp; Johnson. I      23        saw evidence as to what's in the talcum powder      24        products, but I didn't do my own analysis as to      25        what is in the talcum powder products.</p>

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<p>1        But pharmaceutical-grade talc, if we're      2 talking about talc that's used in pleurodesis,      3 for example, is going to be different than talcum      4 powder products in the bottle --</p> <p>5        Q. Okay.</p> <p>6        A. -- cosmetic talcum powder products.</p> <p>7        Q. So how is it different?</p> <p>8        A. So, again, I didn't do my own analysis      9 as to what is in the talcum powder product, but      10 that's what I am -- that's what my general      11 causation opinion is on, is the talcum powder      12 product in the bottle, that regular perineal use      13 of that causes ovarian cancer.</p> <p>14        Q. My question to you is: What do you      15 understand the difference between the talcum      16 powder products and pharmaceutical-grade talc --</p> <p>17        MR. ROTMAN: Objection.</p> <p>18        Q. -- to be?</p> <p>19        A. So I've seen evidence that in talcum      20 powder products, there are heavy metals. There      21 are fragrances that are added to the talcum      22 powder product that, in talc used for      23 pleurodesis, they wouldn't be adding fragrances      24 to that type of talc.</p> <p>25        Q. Would -- you're not saying that talcum</p>	<p>1        A. Well, I think I've answered, like, to      2 me, it doesn't -- it doesn't really matter      3 what -- the difference between pharmaceutical      4 talc and talcum powder products; it's whatever is      5 in that talcum powder products -- product,      6 whatever is in the bottle that women are buying      7 off the shelf and applying to their perineum.</p> <p>8        MR. KLATT: Objection. Nonresponsive.</p> <p>9        MS. AHERN: Objection. Nonresponsive.</p> <p>10        Q. My question was -- originally was: Do      11 you know of any literature that connects talc      12 dust of surgical gloves and any sort of cancer.      13        And then you said, "First of all, I think      14 we're talking about surgical glove talc, which is      15 a pharmaceutical-grade talc, which is different      16 from the talcum powder product that I'm opining      17 about."</p> <p>18        So what I'm asking you is: What is      19 different about the talcum powder product that      20 you're --</p> <p>21        A. It's what I'm opining about. You know,      22 I haven't --</p> <p>23        Q. Right.</p> <p>24        A. -- looked at the talc that's used for      25 pleurodesis, for example. It's what I'm</p>
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<p>1 powder products that are sold to consumers have      2 been altered to add heavy metals, are you?</p> <p>3        A. Well, I've seen the report of      4 Dr. Crowley that looks at heavy metals and      5 fragrances in the talc, the baby product talc      6 powder that he examined. I did not do my own      7 analysis of that.</p> <p>8        Q. Does pharmaceutical-grade talcum powder      9 also have associated metals and sometimes heavy      10 metals?</p> <p>11        A. I'm not sure if I've seen data as to      12 what is specifically in pharmaceutical-grade      13 talcum powder, but, again, to me, what is      14 important is the ultimate product and what is in      15 that bottle. It can -- whether it's platy talc,      16 fibrous talc, asbestos, heavy metals, fragrance      17 metals.</p> <p>18        I mean, to me -- you know, I've seen      19 evidence of those things in that product, but to      20 me, what I'm looking at is the final product when      21 it comes to causing ovarian cancer.</p> <p>22        Q. So what is different about that final      23 product and pharmaceutical-grade talc? What      24 specific components have been added to that that      25 affect your opinions in this case?</p>	<p>1 separating out.</p> <p>2        I've looked at the talcum powder product      3 that women use on their perineum, what they      4 bought off the shelf. I haven't looked at      5 pharmaceutical-grade -- let me correct that --      6 pleurodesis talc, for example. I have not looked      7 at pleurodesis talc and ovarian cancer. I have      8 not looked at any literature specifically on      9 that. It's been the talcum powder products that      10 women are buying off the shelf and using on their      11 perineum.</p> <p>12        Q. So if I told you that Johnson's baby      13 powder starts out as pharmaceutical-grade talc      14 and that, beyond that, fragrance is added, would      15 it be the fragrance that you're taking issue with      16 that you believe is causally associated with the      17 development of ovarian cancer?</p> <p>18        A. Again, I -- it's whatever is in that      19 bottle. It could be platy talc, fibrous talc,      20 asbestos, heavy metals, fragrance. It -- to me,      21 it's the product, whatever the product is that      22 they are using.</p> <p>23        Q. And you have done a biologic      24 plausibility analysis for fragrances, for metals,      25 for asbestos, for fibrous talc, and for platy</p>

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<p>1 talc --</p> <p>2 A. So --</p> <p>3 Q. -- each one of those constituents?</p> <p>4 A. So I have looked at evidence -- so</p> <p>5 Dr. Crowley's report, I mentioned. I've looked</p> <p>6 at Dr. Longo's report. I've looked at Hopkins</p> <p>7 and the Pier charts from their depositions. I'm</p> <p>8 aware of evidence that these heavy metals and</p> <p>9 fragrances and asbestos are in there.</p> <p>10 However, I haven't done -- what I know, I</p> <p>11 looked at the -- I've looked at some literature</p> <p>12 and I've looked at the IARC categorization of the</p> <p>13 heavy metals. I've looked at Dr. Crowley's</p> <p>14 report and I've done an extensive look at</p> <p>15 asbestos and ovarian cancer.</p> <p>16 But, ultimately, those are just pieces of</p> <p>17 biological plausibility. What I'm mainly -- what</p> <p>18 I am opining about is the ultimate product. And,</p> <p>19 again, it can be platy talc, it can be fibrous</p> <p>20 talc, it can be asbestos, it can be heavy metals.</p> <p>21 It's pieces of information that strengthen</p> <p>22 the plausibility. We know that asbestos causes</p> <p>23 ovarian cancer, that certain heavy metals are</p> <p>24 carcinogens, which the IARC categorized them as.</p> <p>25 So it's just -- it's just additional pieces of</p>	<p>1 consistency piece of it.</p> <p>2 Q. Can I ask you -- you can go through all</p> <p>3 of it if you want, but would you rather break it</p> <p>4 down piece by piece?</p> <p>5 MR. ROTMAN: She should answer your</p> <p>6 question.</p> <p>7 MS. AHERN: I'm not sure she's</p> <p>8 answering my question. My question was: How do</p> <p>9 you come up with causation when you don't know</p> <p>10 what the exposure is?</p> <p>11 MR. ROTMAN: I think she's answering</p> <p>12 the question.</p> <p>13 MR. TISI: That wasn't the question.</p> <p>14 The question was: Do you need to know the agent?</p> <p>15 And she said the agent is the product.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. The agent is everything in it?</p> <p>18 A. Yes, the agent is whatever is in that</p> <p>19 talcum powder product.</p> <p>20 Q. So are you basing, then, your causation</p> <p>21 conclusions on the epidemiologic literature</p> <p>22 alone?</p> <p>23 A. The epidemiologic literature is very</p> <p>24 comp--</p> <p>25 MR. ROTMAN: She was not done with her</p>
<p style="text-align: center;">Page 135</p> <p>1 information that strengthen the biological</p> <p>2 plausibility arm of it.</p> <p>3 Q. Doctor, how do you arrive at a</p> <p>4 causation conclusion without a well-defined agent</p> <p>5 of exposure?</p> <p>6 MR. ROTMAN: Objection.</p> <p>7 Q. Do you understand what I'm asking you?</p> <p>8 How do you arrive at your causation and</p> <p>9 conclusion when you're not sure what it is about</p> <p>10 the talcum powder products that's actually</p> <p>11 biologically relevant?</p> <p>12 A. Well, I think -- well, strike that.</p> <p>13 The epi studies are looking at the product</p> <p>14 that the women are using. So that is the agent.</p> <p>15 It's the -- it's the total product. That is the</p> <p>16 agent.</p> <p>17 So when you're looking through -- let me</p> <p>18 just -- so let's keep in mind that we're looking</p> <p>19 at that product.</p> <p>20 And then if you go through my Bradford Hill</p> <p>21 analysis, you look at strength of association.</p> <p>22 And, overall, there's a consistent relative risk</p> <p>23 that's between 1 and 2. I would say it's, across</p> <p>24 studies, averaging 1.3 to 1.4 relative risk, and</p> <p>25 that's consistent across studies. That's the</p>	<p style="text-align: center;">Page 137</p> <p>1 earlier answer. Now you've gone two more beyond</p> <p>2 it.</p> <p>3 MS. AHERN: She's answering. Why don't</p> <p>4 you let her answer. If she wants to go back, she</p> <p>5 can.</p> <p>6 MR. ROTMAN: No, I want her to go back.</p> <p>7 She was -- she was in the middle of going through</p> <p>8 her Bradford Hill to answer your earlier question</p> <p>9 and you cut her off. So she had covered strength</p> <p>10 of association.</p> <p>11 BY MS. AHERN:</p> <p>12 Q. Doctor, you can answer the question the</p> <p>13 way you want to answer the question.</p> <p>14 MR. ROTMAN: Now there's no question in</p> <p>15 front of her.</p> <p>16 MS. AHERN: Well, because you</p> <p>17 interrupted it.</p> <p>18 MR. ROTMAN: Let's go back to what the</p> <p>19 question was before you cut her off. "Do you</p> <p>20 understand what I'm asking you? How do you</p> <p>21 arrive at your causation and conclusion when</p> <p>22 you're not sure what it is about the talcum</p> <p>23 powder products that actually biologically --</p> <p>24 that are biologically relevant?"</p> <p>25 And then you gave -- then you started</p>

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<p>1 an answer about the epi studies are looking at      2 the product that the women are using, and you      3 were talking about strength of association and      4 then you said, "And that's consistent across      5 studies. That's the consistency piece of it,"      6 and then you were interrupted.      7 So were you done with your answer to      8 that earlier question?      9       THE WITNESS: I can continue, because I      10 think it's important.      11       I mean, I was -- my general causation      12 opinion, the methodology I used was to answer the      13 question: Does perineal application of talcum      14 powder products, the, you know, baby powder      15 product that you buy off the shelf, does that      16 cause ovarian cancer? So it's whatever is in      17 that bottle.      18       So with the methodology that I used,      19 looking at the epi data, but also considering the      20 Bradford Hill criteria -- which, you know,      21 looking for specificity is another one. So most      22 of the studies showed a stronger -- a strong      23 association with serous ovarian cancer, but it      24 was basically associated with epithelial ovarian      25 cancer, so all groups of epithelial ovarian</p>	<p>1 generally accepted knowledge of the disease in      2 question.      3       So we know that particles can reach the      4 ovary. We know that talc can cause chronic      5 inflammation. We know that chronic inflammation      6 is associated with certain types of cancer. We      7 know that certain types of ovarian cancer have      8 shown association with chronic inflammatory      9 conditions.      10       So, again, going through all this is      11 experiment and analogy, experiment with the      12 animal studies and the in vitro studies. And      13 analogy, I used the example of asbestos, because      14 even though asbestos is -- you know, asbestos is      15 chemically similar, you can have asbestos fibers      16 and talc fibers, but it's a similar mineral      17 chemically, and we know that that is a      18 carcinogen. So that's part of the analogy.      19       But, again, it's the whole picture. I      20 mean, you look at the -- all of this data      21 following my methodology and you apply the      22 Bradford Hill criteria guidelines -- the Bradford      23 Hill guidelines. And, looking at all that, my      24 professional judgment is that the talcum powder      25 products can cause ovarian cancer.</p>
<p style="text-align: center;">Page 139</p> <p>1 cancer. It was pretty specific, the epi data,      2 for that type of ovarian cancer.      3       Temporality. If you look at that, I      4 mean, the case-control studies are retrospective      5 reviews, so we know that they were using talc      6 before their diagnosis of ovarian cancer.      7       Biological gradient. For those studies      8 that looked at a biological gradient, there was      9 an evident -- there was evidence of a      10 dose-response, not all of the times statistically      11 significant, but the trend -- you can see a trend      12 of a dose-response across studies.      13       And then we get into the plausibility      14 piece, which you've been discussing mostly so far      15 in this deposition, which has to do with the      16 plausible mechanism of talcum powder -- what I'm      17 thinking of, talcum powder products -- whatever      18 is in that bottle was what I'm looking at --      19 talcum powder products causing -- the      20 plausibility of it causing a chronic inflammatory      21 response, leading to ovarian cancer. We've been      22 discussing that quite a bit today.      23       And then coherence. So I can refer      24 again to my report. Coherence, in this context,      25 means coherence between epidemiologic and</p>	<p style="text-align: center;">Page 141</p> <p>1       Q. Okay. Are you done? I don't want to      2 interrupt you.      3       A. I think I answered the question.      4       Q. Okay. One of the things, and I guess a      5 major component of the talcum powder products,      6 would be talc; correct?      7       A. Presumably -- it's called talcum      8 powder, so presumably, talc would be a      9 constituent.      10       Q. Do you know what percentage of talcum      11 powder products is talc?      12       A. Again, I did not do my own analysis as      13 to how much talc was in that product.      14       Q. Do you know whether any of the heavy      15 metals that you looked at or were examined by      16 other experts in this litigation, whether any of      17 those are known carcinogens for the ovary?      18       A. So it's another piece of information.      19 There is not, to my knowledge -- looking at what      20 the IARC looked at, there's not data right now on      21 those heavy metals and ovarian cancer, but      22 it's -- it's a -- it's a piece of the puzzle.      23 It's a piece of information.      24       The IARC has called some of them      25 carcinogenic, some of them probably carcinogenic,</p>

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<p>1 so we know that they can cause cancer. And if      2 they're in the talcum powder products, then it's      3 just another piece to the puzzle of plausibility.      4 Q. Are you saying that the probably      5 carcinogenic category for IARC means that they      6 can cause cancer?      7 A. Well, we can look at what the IARC 2A      8 categorization -- category actually says, what      9 they break it down. But my understanding is      10 it's -- probably carcinogenic means it probably      11 causes cancer, more likely than not, probably      12 causes cancer.      13 Q. How many categories does IARC have?      14 A. They have four.      15 Q. What is the -- what is Category 1?      16 A. Carcinogenic.      17 Q. Known to be carcinogenic?      18 A. Mm-hmm.      19 Q. And then the next?      20 A. Probably carcinogenic.      21 Q. And then?      22 A. Possibly carcinogenic.      23 Q. And then?      24 A. I think it's unclassifiable. I have to      25 look. But I think it's uncertain, basically.</p>	<p>1 little too wide a net. I think science is always      2 evolving and there's always the possibility of an      3 unknown cause of a certain type of cancer.      4 MS. AHERN: Objection. Nonresponsive.      5 Q. My question was just: Can carcinogens      6 be organ specific?      7 A. And I feel like I answered that fairly.      8 Q. Do you know of carcinogens that are      9 organ specific?      10 A. I know -- for example, we know that H.      11 Pylori causes increased risk of gastric cancer,      12 but not oral or esophageal cancer.      13 We know that HPV infection can cause      14 cervical cancer, anal cancer, certain types of      15 squamous cell carcinomas of the oropharyngeal      16 system, but not, you know, of the endometrium,      17 for example.      18 So we know that certain things cause certain      19 cancers and aren't -- haven't been associated      20 with other types of cancers. But to cast that      21 wide a net, to say that a carcinogen is only      22 going to cause one type of cancer or this cancer      23 is caused only by this carcinogen, I think that's      24 too wide a net, because I feel like research is      25 constantly evolving. We're constantly learning</p>
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<p>1 Q. And then what is the last?      2 A. And then known not to be carcinogenic.      3 Q. How many agents are in the known not to      4 be carcinogenic category?      5 A. Very, very few.      6 Q. One; right?      7 A. That's plausible. I haven't looked at      8 the list recently.      9 Q. So going back to the major component,      10 you don't know what percentage of talcum powder      11 products are actually talc?      12 MR. ROTMAN: Objection.      13 A. I have not done my own analysis as to      14 what the components are of that talcum powder --      15 of the talcum powder products.      16 Q. Do you agree that carcinogens can be      17 organ specific?      18 A. I will agree that certain tissues      19 respond to certain things differently.      20 Q. Do you agree that carcinogens can be      21 organ specific?      22 A. Certain tissues respond to certain      23 things differently. If you're casting that wide      24 a net to say that one specific carcinogen only      25 causes one type of cancer, I think that's a</p>	<p>1 of new causal factors in cancer.      2 Q. Do you think that dose is an important      3 consideration when you're looking at the      4 toxicologic effects of an agent on a tissue?      5 A. I think it is a piece of information.      6 I'm looking at my biological gradient portion of      7 my report, and I said in my report that it was an      8 important factor in my analysis because it does      9 add information to the overall causality.      10 Q. Are there agents that can be toxic at      11 certain levels and not toxic at other levels?      12 A. There are certainly agents that are      13 more toxic with increased exposure and increased      14 duration. We don't know all of the thresholds      15 for carcinogenicity of all carcinogens.      16 Q. As part of the biologic plausibility      17 analysis that you would do on a particular agent,      18 would that take into consideration the relative      19 levels of exposure that a person would have to      20 that agent?      21 A. Well, dose-response -- I -- I'm taking      22 it -- your question -- can you rephrase the      23 question? I'm sorry. I just want to make sure      24 I'm answering it accurately.      25 Q. To determine whether it's biologically</p>

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<p>1 plausible for a particular agent to cause a      2 particular harm, would you need to be able to      3 characterize the dose of that agent that is      4 required to elicit the effect that you're looking      5 for?</p> <p>6 A. I think it's a piece of the      7 information -- a piece of information, but you're      8 not always going to be able to determine a      9 dose-response. It's going to depend on the      10 carcinogen, the agent, the routes of exposure.      11 You're just not always going to have that data,      12 unfortunately. It would be nice to have, but      13 you're not always going to have it, and you don't      14 necessarily have to have it to come to      15 plausibility.</p> <p>16 Q. And do you have well-characterized      17 levels of exposure to the ovaries for women who      18 are using talc perineally?</p> <p>19 MR. ROTMAN: Objection.</p> <p>20 A. So some of the -- we're never really      21 going to be able to figure out what an actual --      22 to characterize what an actual dose -- dose of      23 talcum powder product of what -- of a talcum      24 powder product in a particular use. We don't      25 know how much a woman is putting on her hand to</p>	<p>1 and ovarian cancer. I certainly saw some of the      2 data about talc migration and cornstarch on      3 surgical gloves migration, but I didn't      4 specifically -- I don't know if -- I don't even      5 know if that study has really been done.</p> <p>6 Q. Did you consider the publications on      7 talc responses -- or, excuse me, did you consider      8 the publications on granulomatous reactions to      9 talc from surgical gloves to be relevant to your      10 biologic plausibility analysis?</p> <p>11 A. It's a piece of information that      12 talc -- now, again, surgical glove talc, for me,      13 is different than the talcum powder products.</p> <p>14 You know, my general causation opinion -- I      15 just want to be clear -- is about, you know,      16 talcum powder products, not the talc used in      17 pleurodesis, not talc on surgical gloves.</p> <p>18 Having said that, I think it's an important      19 piece of information to know that talc on      20 surgical gloves can cause a granulomatous      21 reaction, because that is further evidence for      22 plausibility that talcum powder products --      23 they're called talcum powder products, so, again,      24 it's sort of an assumption. It doesn't really      25 matter to me what's in there, but my assumption</p>
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<p>1 place into the perineum. We don't know how much      2 of that product is getting to the ovary. We know      3 that it can get to the ovary because we've seen      4 talc in the ovary. But where -- it's extremely      5 difficult in this type of situation, when women      6 use the product differently, to know what the      7 dose -- what a single dose is.</p> <p>8 Now, if you're talking long-term, frequent      9 use of talcum powder products, of course, the      10 exposure is going to be greater than a single use      11 of that product.</p> <p>12 But are we ever going to know what one dose      13 of talcum powder product is? I don't think we're      14 going to be able to say that and how much of one      15 dose reaches the ovary.</p> <p>16 But, certainly, again, with -- over time,      17 increased frequency and duration, it's -- you      18 know, more of that product is going to reach the      19 ovary.</p> <p>20 Q. So going back to the discussion we had      21 earlier about surgical glove talc, do you know of      22 any literature that links exposure to talcum      23 powder -- pharmaceutical-grade talcum powder from      24 surgical gloves to any kind of cancer?</p> <p>25 A. I did not opine on surgical glove talc</p>	<p>1 is that whatever -- the talc or whatever is in      2 that product is causing the -- a chronic      3 inflammation. And so it's part -- it's a piece      4 of evidence for the plausibility.</p> <p>5 Q. So are you not aware of any studies,      6 based on the review that you did conduct, that      7 link surgical glove talcum powder with the      8 development of any cancer?</p> <p>9 MR. ROTMAN: Objection.</p> <p>10 A. So I'm not sure how you could do that.      11 If you're looking at patients who -- I think that      12 would be a very difficult study to design.</p> <p>13 If you're looking at women -- if you're      14 doing a case-control study -- I'm just      15 thinking -- and you're looking at patients who      16 have been diagnosed with ovarian cancer who have,      17 at any time, had surgery during the time period      18 that talc was used on surgical gloves, I think      19 that would be a difficult study.</p> <p>20 Q. My question to you was --</p> <p>21 MR. KLATT: Objection. Nonresponsive.</p> <p>22 Q. My question to you was: Are you aware      23 of any studies or literature that link      24 talc-dusted surgical gloves to the development of      25 any kind of cancer?</p>

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<p>1           MR. ROTMAN: Objection.      2           THE WITNESS: My thing is not --      3           MR. ROTMAN: There's a button you can      4           push.      5           THE WITNESS: Oh, "follow."      6           MR. ROTMAN: Do you see the button      7           that's flashing on the right-hand --      8           THE WITNESS: Yeah.      9           MR. ROTMAN: -- side? If you hit that,      10          it should go to the bottom.      11          THE WITNESS: Okay. I see. Yup.      12          MS. AHERN: And I'll withdraw that,      13          because there's -- the question asked first was,      14          I think, better. I slightly modified it on      15          accident.      16          BY MS. AHERN:      17          Q. Are you aware of any studies, based on      18          your review, that link surgical glove talcum      19          powder with the development of any kind of      20          cancer?      21          And, Doctor, to be clear, I'm only      22          interested in whether you know of a study, not      23          whether one could be conducted.      24          A. Off the top of my head, it's possible      25          that one exists, but I can't come up with one off</p>	<p>1           could be helpful information to my general      2           causation opinion. So it's possible that I did.      3           Q. Is it in your report or cited in any of      4           your reference lists?      5           A. Again, I can look through my whole      6           reference list. It's the same answer. Off the      7           top of my head, I don't know the answer to that.      8           Q. Do you know of any studies or any data      9           that link foreign-body granulomas to the      10          development of any kind of cancer?      11          A. Well, we know that asbestos can cause a      12          granulomatous reaction and asbestos is certainly      13          associated with mesothelioma and lung cancer.      14          Q. Are there other biologic properties of      15          asbestos that contribute to its carcinogenicity?      16          A. It can provoke a reactive oxygen      17          species inflammatory response.      18          Q. Can it disrupt DNA?      19          A. It can based on that mechanism, yes.      20          Q. Have you seen any studies or data      21          suggesting that talcum powder can do those      22          things?      23          A. I've seen studies that show that talcum      24          powder can increase production of reactive oxygen      25          species and can change gene expression in</p>
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<p>1           the top of my head.      2           Q. Do you know of any data linking      3          surgical glove talcum powder with the development      4          of any cancer?      5           MR. ROTMAN: Objection.      6           A. It would be my same answer.      7           Q. That you don't know, but there might      8          be?      9          A. Sitting here right now, I can't come up      10         with a specific study that evaluated ovarian      11         cancer patients who have had surgery with talcum      12         powder gloves.      13          Q. Any cancer. Not ovarian cancer, any      14          cancer.      15          A. Similar. Sitting here right now, I      16          cannot think of one off the top of my head.      17          Q. And wouldn't that have been something      18          you think you would have picked up in your      19          review?      20          A. It's possible that I did. I just said      21          I can't think of it off the top of my head. It's      22          possible that I did at some point.      23          But my -- and, again, I tried to make every      24          effort to be able to identify studies and      25          literature and evidence that were relevant or</p>	<p>1           mesothelial cells. So, yes, I mean -- let me go      2           back to your question.      3           So I would say, yes, there are studies that      4           show talc can cause the production of reactive      5           oxygen species and reactive nitrogen species,      6           which can disrupt DNA, similar to asbestos.      7           Q. How do reactive oxygen and nitrogen      8           species disrupt DNA similar to asbestos?      9           A. Well, it's the reactive oxygen species      10          -- it's part of this feedback loop with -- what's      11          the word I'm looking for? -- tumor factors like      12          COX and TNF alpha. It's related to those types      13          of expressions and an inflammatory response.      14          Q. Are you relying on cell studies?      15          MR. ROTMAN: Objection.      16          A. I have looked at cell studies. The      17          Buz'Zard study is one, and I know Saed has done a      18          lot with myeloperoxidase and ovarian cells. He      19          recently came out with a paper.      20          So it's, again, a piece of information      21          towards the plausibility arm of my general      22          causation opinion.      23          Q. Have you seen any studies in animals or      24          in humans that have linked the specific enzymes      25          that Dr. Saed has evaluated in cell studies to</p>

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<p>1 the development of ovarian cancer?</p> <p>2 A. So there have been some studies that</p> <p>3 have looked at anti-inflammatory drugs, aspirin</p> <p>4 and NSAIDs in particular.</p> <p>5 The data on NSAIDs has been less consistent,</p> <p>6 but the data on aspirin has been consistent, in</p> <p>7 that it lowers the risk of ovarian cancer with</p> <p>8 regular aspirin use.</p> <p>9 And aspirin, one of the mechanisms of action</p> <p>10 is on the cyclooxygenase expression, which is</p> <p>11 similar to the cyclooxygenase expression seen in</p> <p>12 some of the in vitro studies.</p> <p>13 Q. So my question was: Have you seen any</p> <p>14 studies in animals or in humans that have linked</p> <p>15 specific enzymes that Dr. Saed has evaluated in</p> <p>16 his cell studies to the development of ovarian</p> <p>17 cancer?</p> <p>18 MR. ROTMAN: Objection.</p> <p>19 Q. Are you relying, then, on epidemiologic</p> <p>20 studies looking at NSAID and aspirin use?</p> <p>21 MR. ROTMAN: Objection.</p> <p>22 A. I'm saying that the NSAID and aspirin</p> <p>23 use is another piece of information that -- as to</p> <p>24 plausibility, mechanism -- and mechanism of</p> <p>25 regulation of pathways that can result in</p>	<p>1 get it.</p> <p>2 THE WITNESS: Oh, I'm sorry.</p> <p>3 A. "Ovarian cancer may be analogous,</p> <p>4 therefore, to plural mesothelioma, which has been</p> <p>5 shown to be caused by asbestos, a chemical</p> <p>6 similar to talc."</p> <p>7 Q. Is that the complete passage that</p> <p>8 you're looking at?</p> <p>9 A. I believe that is why I had highlighted</p> <p>10 that one, yes.</p> <p>11 Q. You'd agree that this version of</p> <p>12 Blaustein's textbook was published in 1994?</p> <p>13 A. Yes, I am aware.</p> <p>14 Q. Would you agree that a number of the</p> <p>15 risk factors that have been identified here,</p> <p>16 there have been additional studies published on?</p> <p>17 A. Yes.</p> <p>18 Q. Would you agree that alcohol is a known</p> <p>19 risk factor these days for ovarian cancer?</p> <p>20 A. I don't think that's been borne out to</p> <p>21 be the case. But with talc, there's continued to</p> <p>22 be several case controls and meta-analyses which</p> <p>23 have continued to be consistent with the</p> <p>24 increased risk of ovarian cancer cited in the</p> <p>25 studies that were cited here, which I didn't</p>
<p style="text-align: center;">Page 155</p> <p>1 reactive oxygen species and cause an inflammatory</p> <p>2 response.</p> <p>3 MR. KLATT: Objection. Nonresponsive.</p> <p>4 MS. AHERN: Same.</p> <p>5 Q. Let's go back to that. We'll finish up</p> <p>6 this Exhibit 11.</p> <p>7 What was the next page, if any, the last</p> <p>8 page in your photocopy?</p> <p>9 A. Okay. So this is Page 1216 of the</p> <p>10 fourth edition, if I am correct. Give me one</p> <p>11 second while I find it.</p> <p>12 Okay. So the reason why Page 1216 is there</p> <p>13 is because it starts the section on ovarian</p> <p>14 cancer, which then continues on to Page 1217.</p> <p>15 And it says -- the last paragraph on Page 1217</p> <p>16 says, "Other suggested factors affecting ovarian</p> <p>17 cancer risk include talc exposure, a history of</p> <p>18 mumps infection, and alcohol consumption. Talc</p> <p>19 exposure, which has been related to an excess</p> <p>20 risk of ovarian cancer in a number of</p> <p>21 case-control studies, is of interest biologically</p> <p>22 in that ovarian cancer is thought to arise from</p> <p>23 the mesothelium that lines the peritoneal</p> <p>24 cavity."</p> <p>25 MR. ROTMAN: Slow it down so she can</p>	<p style="text-align: center;">Page 157</p> <p>1 actually Xerox. You have the book, so --</p> <p>2 Yes, I agree this was 1994, but taken into</p> <p>3 context of the subsequent studies and literature</p> <p>4 looking at talc and ovarian cancer, I think it's</p> <p>5 still relevant.</p> <p>6 Q. Have there been a number of updates and</p> <p>7 changes to the classification of tumors since</p> <p>8 1994?</p> <p>9 A. Since 1994, sort of semantically. We</p> <p>10 still have the same subtypes of ovarian cancer.</p> <p>11 There's been a new categorization. We talked</p> <p>12 about the Type 1 and Type 2 ovarian cancers.</p> <p>13 So not a complete overhaul in</p> <p>14 categorization; I think just different ways to</p> <p>15 category the same entities, let's --</p> <p>16 Q. Has the --</p> <p>17 A. -- put it that way.</p> <p>18 Q. Sorry.</p> <p>19 Has the understanding of the origin of</p> <p>20 ovarian tumors evolved significantly since 1994?</p> <p>21 A. So this mentions -- we talked about</p> <p>22 this a little bit earlier -- this does mention</p> <p>23 that at this time, in 1994, there was thought</p> <p>24 that ovarian cancer might arise from the</p> <p>mesothelium. So the ovary is covered by a layer</p>

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<p>1 of mesothelium. That's the outer layer. And so 2 in 1994, that was still, I would say -- this is 3 before my residency, a little before my time -- 4 that that was the most common thought, that 5 that's where the ovarian cancer -- cancers are 6 arising from. Now, since then we've discussed 7 some of the other more recent findings of the 8 etiology.</p> <p>9 But, anyway, I just -- I had read this a 10 couple of days ago and, you know, it was -- it 11 was a reference that I think is still relevant 12 because of the -- the subsequent case controls 13 and meta-analyses that were done since then that 14 I think still make it relevant, although, again, 15 I -- we're not -- we're still not absolutely sure 16 where all of these ovarian epithelial tumors are 17 arising from. But we have a little more evidence 18 than we did in 1994.</p> <p>19 Q. And in 1994, the first prospective 20 cohort study had not yet been published; correct?</p> <p>21 A. I believe that is correct.</p> <p>22 Q. So we would be -- these numbers here 23 in -- that are discussed for talc exposure would 24 be, essentially, just the retrospective case 25 controls that had been published up to that point</p>	<p>1 page just because it was a continuation of that. 2 So, yes, I think we're done with the fourth 3 edition.</p> <p>4 Sorry. I'm starting to talk fast because 5 I'm excited for lunch.</p> <p>6 MS. AHERN: We can take a break for 7 lunch, then.</p> <p>8 THE VIDEOGRAPHER: Here ends Media 3.</p> <p>9 Off the record, 1:05 p.m. (Lunch recess was taken.)</p> <p>10 ("Blaustein's Pathology of the 11 Female Genital Tract," Fifth Edition, 12 marked Exhibit 12.) (Excerpt of Blaustein's 13 Pathology of the Female Genital Tract," 14 Fifth Edition marked Exhibit 13.)</p> <p>15 THE VIDEOGRAPHER: Here begins Media 16 No. 4 in today's deposition of Sarah Kane, M.D.</p> <p>17 Back on the record, 1:45 p.m.</p> <p>18 BY MS. AHERN:</p> <p>19 Q. Okay. Hi, Dr. Kane.</p> <p>20 A. Hello.</p> <p>21 Q. I'm looking here at Blaustein's 22 Pathology of the Female Genital Tract, Fifth 23 Edition, which you brought with you here today.</p>
<p>1 or the specific ones --</p> <p>2 A. Yeah. You have the reference list of 3 the reference numbers 47, 69, 70, and 182.</p> <p>4 Q. Cramer? You said 59?</p> <p>5 A. 69.</p> <p>6 Q. Harlow, 92.</p> <p>7 A. 70.</p> <p>8 Q. 70. Hartge.</p> <p>9 And 83.</p> <p>10 A. And 182.</p> <p>11 Q. And Whittemore, 1988.</p> <p>12 A. So, yes, that was before. They only 13 looked up until 1988.</p> <p>14 Q. Okay.</p> <p>15 MR. ROTMAN: Hunter, a good time to 16 take our lunch break? It's been an hour since 17 our last -- since we started.</p> <p>18 MS. AHERN: Sure. I'm sure people 19 could use a bio break too.</p> <p>20 Q. Are these the only pages that you 21 photocopied from this book -- or in -- sorry. 22 Let me rephrase that.</p> <p>23 Have we finished with the photocopy of 24 Exhibit 11 or are there more pages?</p> <p>25 A. I think -- I think I Xeroxed this last</p>	<p>1 I marked it as Exhibit 12 to your deposition. 2 You can have it back.</p> <p>3 A. Okay.</p> <p>4 Q. Thank you. And inside, you brought 5 with you a photocopy of the cover page and also 6 Page 629. I'll hand that back to you. I think 7 there's only one copy. I've marked that as 8 Exhibit 13.</p> <p>9 A. Oh, okay.</p> <p>10 Q. Here you go.</p> <p>11 A. Okay.</p> <p>12 MR. TISI: What was the page? I'm 13 sorry.</p> <p>14 THE WITNESS: 629. Do you want the 15 textbook back?</p> <p>16 Q. Whichever one you'd rather actually 17 pass back to me. Thank you.</p> <p>18 Can you tell us, on Page 629, what 19 information you thought was relevant to your 20 review of the talc issue?</p> <p>21 A. Yes. I believe this is under "Foreign 22 Body." So this is diseases of the fallopian 23 tube. So under "Foreign Body" -- hold on one 24 second. Okay. It says, "Foreign material may be 25 introduced into the tube in the course of</p>

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<p>1 gynecologic investigation, especially 2 hysteroscopic -- I can't say the word, 3 hysterosalpingo -- anyway, HPG, lubricant jelly, 4 mineral oil and starch and talc powder may cause 5 a lipoid or granulomatous salpingitis. An 6 intense phagocytic reaction to introduce lipid 7 material causes" --</p> <p>8 THE COURT REPORTER: Excuse me. 9 A. Sorry. I think that's basically the -- 10 that is the end.</p> <p>11 No. At the very end of the page, it says, 12 "Talc may cause mucosal or serosal granulomas. 13 Examination of all granulomas or foreign body 14 reactions under polarized light is useful in the 15 recognition of these processes. Other disease 16 processes in the tube such as leprosy or 17 amyloidosis are so infrequent that they are of 18 little clinical or pathologic significance."</p> <p>19 Q. How does that information inform your 20 opinions today?</p> <p>21 A. So it's just another -- again, similar 22 to the other things that we reviewed in the other 23 edition, just another piece of evidence that talc 24 causes mucosal and serosal granulomas, and 25 they're talking about the fallopian tube in this</p>	<p>1 experimental studies or animal studies 2 linking talc foreign-body responses to 3 development of cancer? 4 A. From what I can recall in those 5 textbooks, I don't think they went into any more 6 detail than what I've read for you. 7 Q. Okay. What else did you bring with you 8 today? Anything that we haven't covered other 9 than the boxes behind me? 10 A. Correct. I don't think so. Mr. Rotman 11 brought a copy of my report, but that is all. 12 This -- let me look. 13 All of these have been marked already. 14 Yeah. 15 Q. All right. Doctor, you've got a copy, 16 but I'm going to hand you another one. I've 17 marked as Exhibit 14 a copy of your expert report 18 dated November 15, 2018. 19 (Rule 26 Expert Report of Sarah 20 E. Kane, M.D. marked Exhibit 14.) 21 Q. Can you review Exhibit 14 and tell us 22 if this is indeed your expert report dated 23 November 15, 2018? 24 A. Yes. This appears to be my report. 25 Q. And you brought with you earlier an</p>
<p>1 chapter.</p> <p>2 MR. KLATT: Can I interrupt? 3 (Discussion off the record.)</p> <p>4 MR. LOCKE: I'm on right now. Thanks, 5 Mike.</p> <p>6 BY MS. AHERN:</p> <p>7 Q. And, Doctor, did you review any other 8 sections of Exhibit 12, Blaustein, Fifth Edition?</p> <p>9 A. I believe I did. I think in this 10 edition, from what I recall, that was the -- the 11 reference was in the fallopian tube.</p> <p>12 Q. Is that what we just discussed on 13 Page 629?</p> <p>14 A. Yes. 629 was where talc was discussed 15 in the fallopian tube.</p> <p>16 Q. Did you see any other information in 17 any of the Blaustein texts that we reviewed today 18 that suggests that foreign body granulomas caused 19 by talc have been associated with the development 20 of ovarian cancer?</p> <p>21 A. Well, we saw mention of the 22 epidemiologic studies in the fourth edition that 23 we reviewed.</p> <p>24 Q. So other than the epidemiology, is 25 there any reference to pathology studies or</p>	<p>1 updated copy of your CV; correct? 2 A. Yes, I did. 3 Q. Which we marked Exhibit 2. 4 (Document entitled "References 5 Cited and Other Material and Data 6 Considered" marked Exhibit 15.)</p> <p>7 BY MS. AHERN: 8 Q. And Exhibit B to your report was 9 entitled "References Cited and Other Material and 10 Data Considered." I've marked that as Exhibit 15 11 to your deposition. 12 A. Okay. 13 Q. Okay. And Exhibit 15 isn't paginated 14 but consists of 11 pages. The first ten pages of 15 materials consist of 186 items identified by the 16 caption on the top of Page 1 as "Literature"; is 17 that correct? 18 A. I'm sorry. Are you talking about the 19 "References Cited and Other Material and Data 20 Considered," Exhibit 15? 21 Q. Yes. 22 A. Yes. There is a list of 186 literature 23 references. 24 Q. And the materials listed on Page 11 are 25 identified by a caption as "Other Sources" and</p>

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<p>1 include an additional 17 items; is that correct? 2 A. Yes. 3 Q. Okay. So did you prepare Exhibit 15? 4 A. Yes. I did. 5 Q. Did you type this out yourself? 6 A. I did. Yes. 7 Q. Okay. And how did you go about pulling 8 this together? 9 A. I'm -- in what way? 10 Q. Did you keep a running list of the 11 citations as you went and then pull this all 12 together at the end of your report? 13 A. Yes. So what happened is this was my 14 first medical expert witness report I have 15 written. And you'll notice that -- let's see, 16 all of the -- oh, I'm sorry. This doesn't 17 include the January 4th list; right? 18 Q. We'll get there. 19 A. Okay. So that's what I kind of want to 20 explain. What happened is, the reason why you 21 had a January 4th list, is because I wrote 22 this -- the accepted form for published 23 literature is listing literature that you've 24 actually cited within the body of your report, 25 and so it was my misunderstanding. I was not</p>	<p>1 that you -- the list that you got yesterday is 2 stuff that I had reviewed, I believe. I have to 3 look at it. 4 But my point is that list that you got 5 yesterday was varied, and -- when I looked at it, 6 and it was just an effort to be as complete as 7 possible. 8 Q. Okay. And just looking -- we'll get 9 there, but just looking at Exhibit 15, which -- 10 the first ten pages, which are the references? 11 A. Mm-hmm. 12 Q. So do you define the references as the 13 specific sources that you cited within the body 14 of your report? 15 A. These are sources that I cited within 16 the body of my report. 17 Q. And are these the sources that you rely 18 on to support the opinions expressed in your 19 report? 20 A. So these are some of the references 21 that I used. Again, I also had reviewed the 22 subsequent -- the literature and the other data 23 in the subsequent lists. So I would not say this 24 is all-encompassing, but ultimately, with all the 25 lists you have now, I'm hoping that that is</p>
<p style="text-align: center;">Page 167</p> <p>1 aware at first that you guys were going to want a 2 list of everything that I had reviewed. 3 So what I tried to do is this, I think, was 4 turned in at the same time, so Exhibit 15 was 5 turned in at the same time as Exhibit 14, and it 6 has the literature that was cited within the body 7 of the report. 8 And then when I realized I needed to get a 9 list together of everything, as complete a list 10 of everything that I thought I reviewed, I put 11 together the January 4th list, which was -- I had 12 to sort of recreate -- and I kept almost all of 13 those -- all of this literature in different 14 files. 15 I had to do a little bit of recreation 16 because, as I mentioned before, I lost a couple 17 of hard drives during this whole process, which 18 was not fun. But thankfully, I was -- I had 19 backed up a lot of it. 20 So I tried to be as complete as possible. 21 It is possible that there are a few things I 22 reviewed that did not make the list, which I 23 think I realized on the list that you got 24 yesterday there might have been a couple that I 25 had reviewed before, but most of that literature</p>	<p style="text-align: center;">Page 169</p> <p>1 encompassing of at least all of the stuff that I 2 considered. I wouldn't necessarily say "rely 3 on," but at least everything that I considered. 4 Q. Okay. And that was -- my next question 5 was: Do you differentiate between the sources 6 cited here as references and those that you just 7 considered but weren't included as references? 8 A. Not necessarily. These are the ones 9 that ended up getting cited in the report. Now, 10 there were different drafts, which at one point 11 some of the other ones were cited, and there was 12 a little bit of changing it around, which there's 13 a couple -- I think there are a couple of 14 typographical-type errors in a couple of the 15 references because of that. 16 But essentially, there isn't that much of a 17 difference, I would say, except to say that this 18 is the literature that I ended up specifically 19 citing. 20 But all of the literature that I looked at, 21 I considered. 22 Q. Would you say that all of the 23 literature that you looked at, which would 24 include your other sources here on Exhibit 15, 25 your January 4, 2018, reference list, and the</p>

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<p>1 ones served yesterday, January 24th, would you 2 say that you relied on all of those materials? 3 A. No. Well, I at least reviewed those. 4 I would say that I considered them. I wouldn't 5 necessarily say that I relied upon them. 6 Q. And when you consider material, what 7 does that mean to you? 8 A. Well, you know, when I'm -- you can 9 look at my methodology, how I tried to cast as 10 wide a net as possible with the information that 11 I gathered in the information stage. So I wanted 12 to have as much data, as many literature 13 references, expert reports, whatever I could kind 14 of get my hands on that might be relevant to my 15 general causation report. 16 And then I'm reading through those, and 17 that's actually when I started my draft of the 18 report. It really started as sort of notes that 19 I took as I read the different literature 20 references, and I sort of built out from there. 21 Does that answer your question? 22 Q. I think probably so. 23 Did you collect -- did you identify all of 24 the materials in Exhibit 15 yourself, or were 25 some of these provided to you by the plaintiffs'</p>	<p>1 remember, I did my own literature search, read as 2 much as possible, started taking my own notes. 3 And then thought, as I was sort of forming my 4 opinion, thought, you know, it would be nice to 5 know what the defense is saying. And, of course, 6 I think at that point is when I asked, but I 7 don't remember specific timing. 8 Q. And did you specifically -- did you ask 9 for specific defense reports or specific defense 10 reports related to particular expertise? 11 A. If I recall -- I'm looking at this 12 list -- I believe the first request was a more 13 general request. 14 Q. When you say "more general," do you 15 mean for -- 16 A. Meaning -- 17 Q. -- for defense? 18 A. -- I didn't ask for specific names of 19 people. 20 Q. Ah. 21 A. I think at this point, I wasn't 22 necessarily aware of who would have been defense 23 experts. And so I don't remember exactly, but my 24 inclination is that I had asked for a more 25 general sort of representation.</p>
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<p>1 counsel? 2 A. The vast majority of them, I found 3 through my own literature search. Some of them 4 may have been supplied by the plaintiffs' 5 attorneys. A lot of those overlapped with what I 6 had already found; the exception, of course, 7 being documents on the other sources that I would 8 not have had access to on my own. 9 So I had asked for, and in forming my 10 opinion, my general causation opinion, I had 11 asked for defense expert reports so I could get a 12 sense of what the defense experts' opinions were, 13 just to get, you know, the other -- just to get 14 more information. 15 So that's -- so those were definitely given 16 to me by plaintiffs' attorneys. 17 Q. Do you remember, timewise, did you 18 review the defense expert reports and the 19 materials in the other sources earlier on to get 20 a sense of the issues in the litigation and then 21 do your literature search, or the other way 22 around? What was the timing? 23 A. I don't remember exactly. I don't 24 believe I read the -- I'm trying to think timing. 25 I think what I did is -- from what I</p>	<p>1 Q. And can you identify on here which of 2 the other sources are from defense experts? 3 A. Yes. I'll try my best. 4 The Michael Ober expert report was provided 5 by plaintiffs' counsel. The deposition of Alice 6 Blount was also provided by plaintiffs' counsel. 7 Both of the Chodosh, his report and his trial 8 testimony, was provided by plaintiffs' counsel. 9 Samuel Cohen was provided by plaintiffs' counsel. 10 And also -- also, let's see, the Cramer, I 11 wouldn't have access to the Cramer reports on the 12 Byrd and Jacqueline Fox. The expert report of 13 Michael Crowley was given to me. That, 14 obviously, is a plaintiffs' report that was 15 within a day or two of turning in my report. 16 That was very late in the process. 17 John Godleski, I might have asked for by 18 name. Of course, he's a plaintiffs' expert. 19 His, I may have asked for by name because of the 20 Cramer papers. 21 Q. Did you say Cramer was a plaintiff or 22 defense expert? 23 A. Cramer, I believe, was a plaintiff. 24 Q. I wasn't sure. You named him after the 25 defense experts. I'm sorry. I'm just going</p>

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<p>1 through the list. 2 MR. ROTMAN: The list is alphabetical, 3 so she's going down the list. 4 BY MS. AHERN: 5 Q. Yeah. My question was: Which ones are 6 the defense experts? 7 A. I'm sorry. 8 Q. If you're done, you're done. Are there 9 any other defense experts. 10 A. Well, the John Hopkins and Julie Pier, 11 those exhibits and depositions I got from 12 plaintiffs' counsel. 13 I believe that is it, looking at the list of 14 defense reports. 15 Q. Did you want to know what the defense 16 experts had to say about epidemiology? 17 A. I wanted -- yeah. I wanted as much evidence as I could get, so -- 18 Q. Were you aware that the defendants had 19 designated epidemiologists in the litigation who 20 had given reports and testimony? 21 A. I don't know if I was aware specifically of that. 22 Q. Were you aware that the defense had 23 designated a number of gynecologic pathologists 24 25</p>	<p>1 ones that I received. Yes. 2 Q. Is there anyone on this list that's -- 3 that specifically addresses gynecologic 4 pathology? 5 A. I think it's been a long time since I 6 read those reports, but I do remember some of 7 those reports speaking to -- your question was on 8 top. I'm just making sure. 9 Q. Sure. 10 A. Some -- so the gyn onc report 11 definitely went into some gynecologic pathology. 12 Gyn oncs are generally knowledgeable about gyn 13 pathology because we work pretty closely with 14 them. We often show our gyn pathology, for 15 example, at multiconferences, multidisciplinary 16 conferences. 17 So I vaguely remember a gyn onc one going 18 over some gyn path stuff, but my memory is vague 19 because I have not read these in probably over a 20 year. I don't know exactly. 21 Q. Would you be interested in what the 22 epidemiologists that had served reports and given 23 testimony in the litigation the last five years, 24 what they've said? 25 MR. ROTMAN: Objection.</p>
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<p>1 who had given reports and testimony as well? 2 A. Again, I don't know if I was 3 specifically aware of that. No. 4 Q. Would you have, as a pathologist doing 5 an expert report on this litigation, would you 6 have been interested to know what the defense 7 pathologists had said? 8 A. Well, I will take any data that I can 9 get to try to see if it's relevant. I mean, so I 10 had asked for defense reports, and that's what I 11 got. 12 Q. These reports, these other sources, the 13 17 items here were in response to your request, 14 but they were chosen by the plaintiffs' counsel? 15 MR. ROTMAN: Objection. 16 A. I'm not sure how they were chosen or 17 how -- why -- all I know is that I asked for 18 reports, and this is what I received. 19 Q. And you specifically asked for defense 20 reports; right? 21 A. I did. 22 Q. And you got Michael Beer, who is an 23 oncologist; Lewis Chodosh, a cancer biologist; 24 and Sam Cohen, a toxicologist; correct? 25 A. That would appear, from the list, the</p>	<p>1 A. Again, I'll take whatever information or data, you know, I can get that might be 3 relevant. 4 Q. And do you consider expert litigation 5 reports to be data? 6 A. Yes. I think it's data. 7 Q. Okay. Is it the kind of data you rely 8 on in your everyday practice as a pathologist? 9 A. I sort of view they're opinion reports. 10 They're opinion, general causation opinions, and 11 a couple of these are -- I can't remember. All 12 of these were general, I believe, from the 13 defense. 14 So they're professional opinion data, and I 15 would say that's similar to having a consultation 16 with a colleague or a peer. I mean, you know, in 17 my day-to-day practice, I'm certainly asking 18 opinions of colleagues and different specialties 19 or my own specialty, even. Those are 20 professional judgments, professional opinions, 21 looking at their knowledge of the literature or 22 data. 23 So I think it's a good analogy; looking at 24 general causation, professional opinions, is similar to kind of getting a colleague's opinion.</p>

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<p>1       Q. But this is the first time you've 2       relied on litigation reports to inform your own 3       opinions; correct?</p> <p>4       A. Well, again, I don't know if I would 5       use the word "rely." I certainly considered 6       them, you know. But, again, I think it's very 7       similar to asking a colleague in my daily 8       practice for an opinion on something.</p> <p>9       Q. And, Doctor, looking at 186 references 10      that are cited in Exhibit 15.</p> <p>11      Did you review each one of these carefully 12      and thoroughly?</p> <p>13      A. I reviewed each one of them, some of 14      them probably more thoroughly than others, 15      depending on what I was looking for; but yes, I 16      reviewed all of them.</p> <p>17      Q. And do you know whether or not the 18      boxes, the four boxes that are sitting behind me, 19      do those include these 186 references on 20      Exhibit 15?</p> <p>21      MR. TISI: Let me see if I can help you 22      out.</p> <p>23      MS. AHERN: Sure. Go ahead.</p> <p>24      MR. TISI: My understanding is they do.</p> <p>25      MS. AHERN: That's the 186?</p>	<p>1       But I don't believe I -- well, I might 2       have referenced the Longo. 3       BY MS. AHERN: 4       Q. Page 5. I think if you look at Page 5 5       of your report, you reference Dr. Blount -- 6       A. Yes. 7       Q. -- Dr. Crowley, Longo, Rigler, 8       Hopkins -- 9       A. Yes. 10      Q. -- Pier? 11      A. Yes. Looking back at the list, you're 12      absolutely correct. I did. 13      Q. Do you think, as you sit here, that 14      those are -- 15      MR. TISI: I can look at them if it 16      makes your life easier. I'm happy to do it. 17      But I do think -- Mike is back there 18      looking. I'm thinking that those are the actual, 19      relied-on referenced materials, not the materials 20      considered, which was a separate list. 21      MS. AHERN: That's the January 4th, and 22      we're going to get to that one. 23      MR. TISI: No. it's in the back of the 24      report. Maybe I'm wrong. 25      MS. AHERN: There are other sources,</p>
<p>1       MR. TISI: That would be the references 2       in the report. It would not be, to my -- I 3       haven't cracked the boxes, so I can only assume 4       from past prologue that the information 5       considered is not in those boxes. They may be, 6       but the information relied on that is cited in 7       the report are.</p> <p>8       MS. AHERN: Okay. So other sources 9       here that are not cited specifically, well, they 10      may be --</p> <p>11      MR. TISI: I don't know, for example -- 12      well, maybe we can open them up. But I don't 13      know, for example, if the expert reports and 14      depositions are in the -- in there. If they're 15      cited, then they're probably in there. If 16      they're not cited --</p> <p>17      THE WITNESS: I'm not sure because -- 18      I'm not sure I cited these in my report because 19      they weren't necessarily reliance. It was more 20      data.</p> <p>21      But I thought at the time that I should 22      list what -- because these aren't publicly -- I 23      don't believe any of these are publicly 24      available, what is on this list, so I felt like I 25      should list them.</p>	<p>1       but she has apparently relied on them -- 2       MR. TISI: That's fine. 3       MS. AHERN: -- to some extent in 4       performing reviews about fragrances and asbestos. 5       BY MS. AHERN: 6       Q. Is that right, Doctor? 7       A. Dr. Crowley's report and Dr. Longo's 8       report, yes. I -- 9       Q. And what about Dr. Hopkins and Pier? 10      A. Yes. I don't believe I read their 11      entire depositions. I know I had seen the 12      exhibits from the depositions, and I think 13      part -- I listed it here, so I must have at some 14      point. 15      MS. AHERN: Okay. So let's put 15 over 16      here, and let's move on to the next one. 17      (Document entitled "Additional 18      Material Considered" marked Exhibit 16.) 19      BY MS. AHERN: 20      Q. Okay. Doctor, I'm handing you what's 21      been marked as Exhibit 16 to your deposition. 22      Can you take a look at Exhibit 16 and tell 23      us what that is? 24      A. Yes. So this is a combination. So 25      once I realized that I needed to give you all a</p>

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<p>1 list of -- as complete a list as I could -- I'm 2 not going to say this is a complete list -- and, 3 of course, you have another list that you just 4 got, but I tried to be as complete as I could in 5 recreating the literature and other reports that 6 I had considered.</p> <p>7 So these are ones that, to my recollection, 8 I didn't specifically cite or were not 9 available -- I mean, obviously, I have some of 10 the plaintiffs' expert reports that weren't 11 available to me until after I had written and 12 submitted my report. So some of these were 13 available to me only after -- and the Health 14 Canada came out after my report.</p> <p>15 So these are a combination of things I 16 reviewed subsequent to November 15th and stuff 17 that I had reviewed prior to that but had not 18 specifically cited and recreated the list.</p> <p>19 Q. Okay. And just for the record, this 20 is -- Exhibit 16 is a four-page document. It's 21 not paginated, but it has 96 items identified as 22 "Additional Materials Considered," so -- served 23 on January 4, 2018.</p> <p>24 Can you identify, as you look through these 25 items on Exhibit 16, which of those you reviewed</p>	<p>1 A. No. 2 Q. And are there some materials on 3 Exhibit 16 that were provided to you or 4 identified for you by the plaintiffs other 5 than -- and I'm not talking about the litigation 6 materials, but the articles? 7 A. Again, there might have been some that 8 overlapped with what I had already found. I'm 9 looking. 10 I believe the April 2014 FDA letter may -- 11 although that might have been available on the 12 internet. I might have come across that on my 13 own first. 14 No. I believe the vast majority of this 15 stuff was stuff that I -- other than those 16 reports was stuff that I had independently 17 already found. That's the only one that is 18 ringing a bell as a possibility, but I also seem 19 to remember finding it on the internet. 20 Q. Okay. And are any of these materials, 21 materials that you explicitly rely on or, excuse 22 me, are any of the materials on Exhibit 16 23 materials that you rely on to support your 24 opinions? 25 A. Again, it's all data that I considered.</p>
<p style="text-align: center;">Page 183</p> <p>1 prior to the submission of your report and which 2 ones you reviewed after?</p> <p>3 A. I can do the best that I can. My 4 memory might be a little -- and I have to jog my 5 memory a little bit on some of them.</p> <p>6 Clearly, the expert reports that were 7 dated -- the plaintiff expert reports that were 8 dated after my report, I had not seen --</p> <p>9 Q. Mm-hmm. 10 A. -- prior. 11 And, again, the Health Canada came out 12 afterwards, so that was not available when I 13 submitted my report. The majority of the rest of 14 the literature, I had read prior to submitting my 15 report.</p> <p>16 Q. Okay. Had you seen any draft reports 17 from any of the other experts designated by the 18 plaintiffs in this litigation?</p> <p>19 A. Not before my report. I didn't see any 20 drafts. I only saw the final reports after my 21 report was submitted.</p> <p>22 Q. Okay. Did you have an opportunity to 23 talk with any of the other experts that were 24 designated by plaintiffs prior to your report 25 being submitted?</p>	<p style="text-align: center;">Page 185</p> <p>1 I didn't specifically cite them, but there's 2 certainly pieces of information that helped me 3 come to my conclusion. 4 Q. And you prepared Exhibit 16, didn't 5 you? 6 A. Yes. 7 Q. And do you remember when you prepared 8 it? 9 A. Very shortly before you received it. 10 So it would have been -- you received it 11 January 4th? 12 Q. Mm-hmm. 13 A. I think I -- it was only -- I don't 14 remember exactly, but it wasn't very long before 15 that that I put it all together, after 16 recreating -- trying to recreate as best I could 17 the list of literature that I had reviewed. 18 Q. And did you carefully and completely 19 review all of the information in Exhibit 16? 20 A. Again, I reviewed all of it. Some of 21 it was more relevant than others, likely, so -- 22 but I reviewed all of them. 23 Q. Okay. Obviously, anything that you 24 received after your report is information you 25 would not have relied on to form your opinions in</p>

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<p>1 this case; correct?</p> <p>2 A. No. It's more information for my -- my</p> <p>3 opinion hasn't changed since I wrote my report.</p> <p>4 In fact, I know we've talked about Health Canada</p> <p>5 a little bit, but that was pretty interesting to</p> <p>6 see that report because their methodology was</p> <p>7 very similar to mine, and they did a Bradford</p> <p>8 Hill analysis, and they looked at a lot of the</p> <p>9 same literature and came to the same conclusion.</p> <p>10 So that definitely was supportive evidence,</p> <p>11 I think -- not I think; it is -- of my opinion.</p> <p>12 Q. And, Doctor, I only have one copy of</p> <p>13 this. It's "Additional Materials to Sarah Kane"</p> <p>14 that were served last night or yesterday</p> <p>15 afternoon, January 24th.</p> <p>16 (Document entitled "Additional</p> <p>17 Materials to Dr. Sarah Kane" marked Exhibit</p> <p>18 17.)</p> <p>19 BY MS. AHERN:</p> <p>20 Q. First of all, can you take a look at</p> <p>21 that?</p> <p>22 Have you seen it before?</p> <p>23 A. Yes. Yes. I have.</p> <p>24 Q. Did you prepare that?</p> <p>25 A. I did. I had listed -- there are a</p>	<p>1 I think that covers most of them.</p> <p>2 Q. What about the EFSA guidance on the use</p> <p>3 of weight of evidence?</p> <p>4 A. Oh, yeah. That, I think, I reviewed</p> <p>5 after I had submitted my report.</p> <p>6 Q. Did that form part of the basis of your</p> <p>7 opinions or your methodology?</p> <p>8 A. It was more of a -- it basically shows</p> <p>9 that the methodology that I used is very similar</p> <p>10 to evidence-based medicine that we would use on a</p> <p>11 daily basis. It kind of went through weight of</p> <p>12 evidence, and it was sort of helpful to see the</p> <p>13 similarity of the methodology that I used coming</p> <p>14 to my conclusion.</p> <p>15 Q. Was the methodology you used for</p> <p>16 preparing your opinions in this case and your</p> <p>17 report in this case taken directly from the EFSA</p> <p>18 guidance?</p> <p>19 A. No. I think I just -- I saw this EFSA</p> <p>20 guidance after writing my report.</p> <p>21 Q. Did you use any other sort of published</p> <p>22 methodology on weight of the evidence when you</p> <p>23 prepared your opinions?</p> <p>24 A. I used what we have been trained to</p> <p>25 use. I mean, it's evidence. It's an</p>
<p>1 couple of papers that I realize I had read</p> <p>2 previously and didn't -- I can tell you Purdie,</p> <p>3 1995, Keskin, 2009, I definitely reviewed while</p> <p>4 preparing my report, and somehow those got off</p> <p>5 the list.</p> <p>6 The other ones, Taher wasn't available. I'm</p> <p>7 trying to remember Gordon, if I had seen that.</p> <p>8 If I had seen that before I submitted a report,</p> <p>9 it was very late. It might have been after.</p> <p>10 The IARC heavy metals, I believe I actually</p> <p>11 cited that in my reference list, but I was trying</p> <p>12 to be -- it was one of these last-minute, trying</p> <p>13 to be as complete as possible, so that actually</p> <p>14 might be a repeat.</p> <p>15 The website, I had reviewed prior to turning</p> <p>16 in my report. And the Longo supplemental report,</p> <p>17 obviously, wasn't available until January. Same</p> <p>18 with the depositions. Those weren't available</p> <p>19 until after they were done.</p> <p>20 The Kurman defense report, I asked for</p> <p>21 recently when I realized that Kurman was a</p> <p>22 listed -- a named expert witness, which is also</p> <p>23 why I went through my copies of my old textbooks</p> <p>24 and my partner's old textbooks. So that, I asked</p> <p>25 for specifically.</p>	<p>1 evidence-based medicine model of methodology and</p> <p>2 coming to conclusions. So it's -- I tried to do</p> <p>3 as thorough as possible description of my</p> <p>4 methodology, which we can refer to in my report</p> <p>5 if you'd like.</p> <p>6 Q. What about the J&amp;J Science Day</p> <p>7 presentation?</p> <p>8 A. That --</p> <p>9 MR. ROTMAN: Objection. Is there a</p> <p>10 question?</p> <p>11 MS. AHERN: I'm about to get there if</p> <p>12 you'd let me finish my question.</p> <p>13 MR. ROTMAN: I thought you were.</p> <p>14 Sorry.</p> <p>15 MS. AHERN: You might just hold off.</p> <p>16 BY MS. AHERN:</p> <p>17 Q. What about the J&amp;J Science Day</p> <p>18 presentation? Is that something that you</p> <p>19 reviewed?</p> <p>20 A. I reviewed that very quickly, and I</p> <p>21 only received that maybe a week ago. It was very</p> <p>22 recently.</p> <p>23 Q. Did you request that information?</p> <p>24 A. I think, from what I remember, it was</p> <p>25 part of asking for more sort of defense side of</p>

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<p>1 the story; what, you know, your experts might 2 have been saying; what kind of -- you know, I was 3 trying to figure out how somebody who had looked 4 at the same body of evidence that I did can come 5 to a different conclusion, so it was part of sort 6 of that request.</p> <p>7 I think I probably got it after I requested 8 Kurman's defense report from a prior litigation, 9 if memory serves me correctly.</p> <p>10 Q. You would agree that a very large part, 11 not just volume, but a very large part of your 12 report and your opinions in this case are related 13 to the observational epidemiology on talc and 14 ovarian cancer; is that correct?</p> <p>15 A. Well, I think that epidemiology 16 literature is extremely compelling. You have 17 30 case-control studies over different periods of 18 time in different populations that have come to 19 the same -- same ballpark relative risk, I would 20 say, 1.3 to 1.4.</p> <p>21 Now, not all of those have been 22 statistically significant, but some of those 23 studies were smaller studies, and so that tends 24 to decrease the power of the study and your 25 confidence intervals will be wider.</p>	<p>1 is such a rare disease, and you're sort of, you 2 know, rolling the dice when you enroll patients 3 as to whether or not they're going to end up with 4 a disease at the end that you want to study. 5 So you're sort of -- and these cohorts are 6 also designed for multiple endpoints and multiple 7 diseases. They weren't just looking, most of 8 them -- I believe the sister -- well, the sister 9 study -- anyway, we can pull it out if I have to, 10 but my point is the cohort studies are designed 11 for multiple different things, especially the 12 Nurses' Health Study. 13 And so it's a difficult type of study to 14 design with a very rare disease. And I think 15 that's where the case-control studies are 16 important because you can start with the disease 17 and work backwards, and so you can have an easier 18 time getting cases. 19 Q. Did you find it interesting or odd that 20 you were provided with a number of defense expert 21 reports, but not a single one of them related to 22 the epidemiology specifically from an 23 epidemiologist? 24 A. Well, you know, again, I don't pretend 25 to know why I was sent what I was sent. I just</p>
<p style="text-align: center;">Page 191</p> <p>1 But I thought the epi data was really 2 compelling. And often in causation, the epi data 3 sort of leads the way in paving a path to 4 figuring out causation. 5 A perfect example is tobacco. You know, the 6 Surgeon General issued his report in the 1960s 7 about tobacco before they had any mechanism for 8 tobacco causing -- so that was a perfect example 9 of the epi data leading to causation. 10 So it's true, a lot of the studies looking 11 at talcum powder products and ovarian cancer are 12 epidemiology studies, but they're extremely 13 informative in that they are very consistent in 14 their findings. And, again, different authors, 15 different populations, different countries. 16 And there's also the cohort. So I went 17 through the cohort studies. The cohort studies, 18 some of them showed an association with serous 19 invasive carcinoma, but the cohort studies didn't 20 tend to find, other than that, a statistically 21 significant increased risk, although some of them 22 did find increased risk. 23 But we can talk about cohort studies versus 24 case-control studies if you want, but I think the 25 difficulty with cohort studies is ovarian cancer</p>	<p style="text-align: center;">Page 193</p> <p>1 know that I asked for reports, and I got what I 2 got. So I have no idea what the process was in 3 deciding what I received; if there was even a 4 decision. For all I know, it's just what they 5 had readily available. 6 Sorry. What is the question? 7 Q. Well, let me ask another question. 8 MR. ROTMAN: Let her finish the answer 9 because you can read -- she can go back and read 10 from the realtime what the question was and see 11 if she's done. 12 A. So I guess I don't know if there was 13 thinking -- what the thinking was or if there was 14 any. But also I can say that the epi data -- I 15 knew that by that point that the epi data was 16 consistent by the time I -- I think that was the 17 first literature that I was looking at, and so I 18 knew that it was consistent. 19 So it's -- anyway, I don't really -- I don't 20 know is the answer, the short answer. 21 The long answer, the short answer is I don't 22 know why I got what I did. I just did. 23 Q. Okay. And you've seen the designations 24 in this case from November of 2017 in which you 25 were listed formally and publicly as an expert</p>

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<p>1 for the MDL? Have you seen that document?</p> <p>2 A. I'm not sure that I have, actually.</p> <p>3 Q. Were you aware that in November of</p> <p>4 2017, you were listed on a court document as an</p> <p>5 expert for the plaintiffs in the MDL litigation?</p> <p>6 MR. ROTMAN: Objection.</p> <p>7 A. I don't know the timing or I don't</p> <p>8 think I saw the document, so I...</p> <p>9 ("The Plaintiffs' Steering</p> <p>10 Committee's Initial Designation and</p> <p>11 Disclosure of Non-case Specific Expert</p> <p>12 Witnesses" marked Exhibit 18.)</p> <p>13 BY MS. AHERN:</p> <p>14 Q. Okay. I'm marking Exhibit 18 to your</p> <p>15 deposition. Do you see this document,</p> <p>16 Exhibit 18, is entitled "Plaintiff Steering</p> <p>17 Committee's Initial Designation and Disclosure of</p> <p>18 Non-case Specific Expert Witnesses"?</p> <p>19 A. Okay.</p> <p>20 Q. And if you turn to -- first of all,</p> <p>21 let's see. Unfortunately, I can't find the date</p> <p>22 on that, and I apologize.</p> <p>23 MR. TISI: It's January, if I'm not</p> <p>24 mistaken. I think it was mid-January of 2017.</p> <p>25 MS. AHERN: Is that what it is?</p>	<p>1 MR. TISI: That's fine.</p> <p>2 MS. AHERN: Absolutely.</p> <p>3 I have the date as November 6, 2017.</p> <p>4 MR. TISI: You are exactly -- well, it</p> <p>5 is what it is.</p> <p>6 MS. AHERN: Okay. Either way.</p> <p>7 BY MS. AHERN:</p> <p>8 Q. Okay. Doctor, if you turn to -- if you</p> <p>9 turn to Page 8, the bottom of Page 8, do you see</p> <p>10 your name?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And did you -- go ahead and</p> <p>13 review the text here associated with your name</p> <p>14 and designation.</p> <p>15 (Witness complies.)</p> <p>16 Q. Just let me know when you're finished.</p> <p>17 A. I'm finished reading my blurb. I'm</p> <p>18 just looking...</p> <p>19 Q. Sure.</p> <p>20 A. Okay.</p> <p>21 Q. Were you aware in November of 2017 that</p> <p>22 you had been publicly disclosed as an expert on</p> <p>23 behalf of plaintiffs in the MDL?</p> <p>24 MR. TISI: Okay. That's -- and you do</p> <p>25 kind of need to know the context in which this</p>
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<p>1 MR. TISI: Yeah. And, Counsel, since I</p> <p>2 was involved in this process, if you don't mind</p> <p>3 if I place an objection here.</p> <p>4 MS. AHERN: Sure.</p> <p>5 MR. TISI: As you may not know, during</p> <p>6 the status conference where this was ordered -- I</p> <p>7 don't have the transcript in front of me -- it</p> <p>8 was intended to be an interim -- I don't know</p> <p>9 what the questions are going to be, but it was</p> <p>10 intended to be an interim disclosure to help</p> <p>11 guide the legal process for identifying issues</p> <p>12 that would be involved in Judge Wolfson looking</p> <p>13 at the science.</p> <p>14 It was never -- I don't know -- again,</p> <p>15 not knowing what your questions are, I don't even</p> <p>16 think it would be intended to be used as an</p> <p>17 expert -- as an exhibit in a deposition.</p> <p>18 But, you know, whatever your questions</p> <p>19 are, we would like to reserve that because --</p> <p>20 MS. AHERN: Sure.</p> <p>21 MR. TISI: -- this was intended to be</p> <p>22 a -- more of an informative document than</p> <p>23 anything else.</p> <p>24 MS. AHERN: Okay. Your objection is</p> <p>25 noted.</p>	<p>1 was done.</p> <p>2 MS. AHERN: I'm just asking if she was</p> <p>3 aware she was publicly -- she was already</p> <p>4 retained at that point.</p> <p>5 MR. TISI: She was retained, but there</p> <p>6 was no -- the judge was very clear when she</p> <p>7 ordered that this be done. She understood that</p> <p>8 this was not a disclosure of experts.</p> <p>9 So when you ask the question "You</p> <p>10 understand you were being identified as an expert</p> <p>11 at that time," she would have no way of knowing</p> <p>12 that because we didn't know it.</p> <p>13 MR. KLATT: Chris, you've got to limit</p> <p>14 your objection.</p> <p>15 MR. TISI: No. But it's unfair</p> <p>16 because --</p> <p>17 MR. KLATT: You're coaching the</p> <p>18 witness. You're telling her the whole story.</p> <p>19 MR. TISI: It's a true story. Why</p> <p>20 don't we ask her to leave, and we'll put it on</p> <p>21 the record. I have no problem with that.</p> <p>22 MR. KLATT: All right.</p> <p>23 MR. TISI: We can ask her to leave, and</p> <p>24 we can put it on the record.</p> <p>25 MR. KLATT: Let's do that.</p>

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<p>1           MR. ROTMAN: Go get a cookie. 2           MS. AHERN: Sorry, doctor. 3           (Witness exited) 4           MS. AHERN: My questions on this are 5           fairly limited to the time period that she was 6           retained, time period she was intending to be an 7           expert, that sort of thing -- 8           MR. TISI: Yeah. 9           MS. AHERN: -- and the subject matter 10          that she is being designated for. 11          MR. TISI: Yeah. But, you see, the 12          issue in the case -- and the reason why this was 13          a tricky issue for the judge and -- well, I won't 14          speak for the judge, but for us when we disclosed 15          this was because we didn't know -- we didn't have 16          expert reports. We didn't even have opinions 17          yet. 18          So this was being done in a way that 19          said, "Okay, Judge, she wants to know, A, are 20          there new and different witnesses that were going 21          to be designated that were different than what 22          was designated in the state court?" 23          MS. AHERN: I do recall this, yes. 24          MR. TISI: The second issue, she was 25          very clear that she understood that there was a</p>	<p>1           MR. TISI: She was probably not, I 2           mean, what she was aware of when she had been 3           retained. 4           MS. AHERN: Did she agree to be 5           disclosed as an expert? 6           MR. TISI: She agreed to be retained. 7           She was disclosed as an expert when she reached 8           her conclusions in the case. 9           And so what the Court was requiring us 10          to do was to give us a broad brush, and she was 11          very clear. I remember standing in court, and 12          she said, "Look, some of these may fall off your 13          list. Some of these may -- we may have people 14          that might be added, but I want a snapshot in 15          time as to what I'm dealing with in terms of" -- 16          MR. KLATT: We don't need to waste time 17          on the record on this. 18          MR. TISI: We can go off the record if 19          you want. I just don't want to be -- use this as 20          an unfair -- you know, none of your questions 21          have been unfair up until now. 22          But to take this document and to 23          suggest in some fashion -- and I don't know what 24          you're going to do with it. Maybe we just need 25          to wait and see.</p>
<p style="text-align: center;">Page 199</p> <p>1          lot of discovery that needed to be done, 2          documents to be reviewed, science that was going 3          to come out. So she was pretty clear that this 4          was more informative than anything else. 5          And so when you ask her a question 6          about -- when you ask her questions, "You know 7          when this document was disclosed when you were 8          identified as an expert," you know, it implies 9          that she had agreed to be -- you know, what her 10         opinions actually were at that time. 11         She -- I can tell you that these 12         reports were done over a period of time. So it's 13         misleading, and it really is an unfair thing to 14         do to a witness because this was a court request 15         having nothing to do with her opinions or her 16         expert report. 17         MS. AHERN: Okay. 18         MR. TISI: Do you understand where I'm 19         coming from? 20         MS. AHERN: I understand where you're 21         coming from. 22         Here is my question to you: Did Dr. -- 23         was Dr. Kane not aware that you were going to 24         designate her or that you had at least publicly 25         disclosed her to the Court?</p>	<p style="text-align: center;">Page 201</p> <p>1          But I think this is -- I don't think 2          anyone ever intended that this document would be 3          used as an exhibit in a deposition of one of 4          these witnesses. I don't think the court 5          intended that to be the case, just like she -- 6          when she ordered the Tardek report -- 7          informational only. 8          MR. KLATT: Are we off the record? 9          We're just going on here. Let's go off the 10         record. 11         MR. TISI: Yeah. 12         THE VIDEOGRAPHER: Off the record, 13         2:38 p.m. 14         (A recess was taken.) 15         THE VIDEOGRAPHER: Back on the record, 16         2:42 p.m. 17         (Witness returns) 18         BY MS. AHERN: 19         Q. Okay. Doctor, I've just shown you a 20         copy of some early designations that were 21         submitted in the talc MDL, and you saw your name 22         listed as one of the people who was being 23         considered as an expert; correct? 24         A. My name is in this document. Yes. 25         Q. Okay. Is there any -- do you have any</p>

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<p>1 issues with the description of the testimony that 2 you were going to offer to give? 3 A. I believe that to be accurate. 4 Q. Okay. And you had been working on your 5 report at this point since May of 2017; correct? 6 A. I started in May. "Writing the report" 7 is a very loose description. What I was -- what 8 I started, as I mentioned before, was I started 9 to review literature. I sort of took notes. So 10 I sort of counted that as writing. So I started 11 that process in May. 12 Q. Okay. And the only thing I was going 13 to ask you about in this report is, as you look 14 through it, do you note that there are a number 15 of professional epidemiologists that have been 16 listed in this report on behalf of plaintiffs? 17 A. I'd have to go through the list. I 18 actually, even though I did have access to 19 several final reports, after I had submitted my 20 report, I don't remember who was what specialty, 21 what field, for the majority of them. 22 Q. Well, how about this question: Of the 23 experts -- are you aware of which experts have 24 submitted reports on behalf of the plaintiffs? 25 A. I would need to look at the list that I</p>	<p>1 asked me if I would be willing to do an extensive 2 review of the literature and decide what my 3 opinion would be on talcum powder products 4 causing ovarian cancer. 5 Q. Did you ask them or discuss with them 6 what your role would be in terms of your specific 7 area of expertise in anatomic pathology? 8 A. I did not specifically talk to them 9 about that because I know that I'm a gynecologic 10 pathologist, so I thought that would be my area 11 where I weigh in on my opinion. 12 Q. And where in your report specifically 13 do you address your expertise in gynecologic 14 pathology, anatomic pathology? 15 A. I list it in the beginning of my 16 report, I think. I talk about -- I talk about my 17 background. 18 Is that what you mean? 19 Q. I mean more in terms of the opinions 20 that you're giving being informed by your 21 expertise in anatomic pathology. 22 A. Well, again, I'm an expert in 23 gynecologic pathology, and the question is about 24 a causation of ovarian cancer, so certainly that 25 falls into my area of expertise.</p>
<p style="text-align: center;">Page 203</p> <p>1 reviewed, which I think is all of the ones that 2 were submitted, and compare it to this list. 3 I mean, I know Jack Siemiatycki is an 4 epidemiologist, off the top of my head. 5 Dr. Singh, I believe, is an epidemiologist. 6 But without going through the list and sort 7 of jogging my memory as to the reports, I skimmed 8 a lot of these reports. 9 Q. Okay. And I guess the point is: Are 10 you aware, as we sit here today, that the 11 plaintiffs have designated a number of 12 epidemiologists in this MDL litigation who have 13 given reports and/or testimony at this point on 14 the topic of epidemiology, talc and ovarian 15 cancer? 16 A. I am aware that they have 17 epidemiologists that have submitted reports for 18 this MDL. 19 Q. Okay. And specifically, if you can 20 think back to your initial contact with 21 plaintiffs' counsel when you were asked to get 22 involved in the litigation, what specifically 23 were you asked to do, or what was your 24 understanding of what your role would be? 25 A. Yeah. My understanding was they had</p>	<p style="text-align: center;">Page 205</p> <p>1 Q. And do you specifically address in 2 terms of anatomic pathology or ovarian cancer 3 pathogenesis the question of talc and ovarian 4 cancer? 5 A. I think that goes to the plausibility, 6 the mechanisms, as part of it. 7 Q. And which particular mechanisms are 8 informed by the discipline of anatomic pathology 9 and gynecologic pathology? 10 A. Well, I think pathologists, anatomical 11 and clinical pathologists, have training in 12 inflammation and immunology and certainly 13 epidemiology, looking at epidemiologic studies. 14 I think all of it is within the realm of 15 gynecologic pathology. 16 Q. Did you discuss anywhere specifically 17 in your report the biology of foreign body 18 reactions and granulomas as a part of the 19 biologic plausibility for exposure? 20 A. Let me refer to my report. I 21 definitely talk about inflammation. I can do a 22 word search for granulomas, if you would like. 23 Q. Do you talk about inflammation -- 24 MR. ROTMAN: Would you like -- 25 Q. -- in the context of anatomic</p>

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<p>1 pathology?</p> <p>2 MR. ROTMAN: Would you like to do that?</p> <p>3 Because I can get your report up electronically.</p> <p>4 MS. AHERN: I know where she's</p> <p>5 mentioned granulomas. I already know. I'm just</p> <p>6 asking her if she knows.</p> <p>7 MR. ROTMAN: So she wants to find it</p> <p>8 quickly.</p> <p>9 MS. AHERN: You can give her your</p> <p>10 computer and let her search.</p> <p>11 MR. ROTMAN: Okay. That's what I was</p> <p>12 asking.</p> <p>13 BY MS. AHERN:</p> <p>14 Q. Do you cite any publications describing</p> <p>15 the biology of granulomas?</p> <p>16 A. I know some of the literature talks</p> <p>17 about granulomatous inflammation, discusses</p> <p>18 granulomatous inflammation.</p> <p>19 MR. ROTMAN: If you want to search, do</p> <p>20 you know how to do it on this computer? Edit,</p> <p>21 Find, then you can type in a word that you want</p> <p>22 to search.</p> <p>23 MR. KLATT: Is there a question?</p> <p>24 A. So I mention it in the animal studies,</p> <p>25 injecting talc into the pleural spaces causes</p>	<p>1 any other portions of your report that directly</p> <p>2 address ovarian cancer pathogenesis from a</p> <p>3 pathology standpoint," and --</p> <p>4 A. So my answer is I did the work, but I</p> <p>5 can't discuss it because of attorney work product</p> <p>6 issues.</p> <p>7 Q. Okay.</p> <p>8 MR. ROTMAN: You can -- she can -- you</p> <p>9 can ask her questions about it.</p> <p>10 MS. AHERN: Sure.</p> <p>11 MR. ROTMAN: But she's -- as to what is</p> <p>12 in the report or not in the report, that's the</p> <p>13 work product piece.</p> <p>14 MS. AHERN: That's kind of all the</p> <p>15 questions.</p> <p>16 MR. ROTMAN: Ask her about the science.</p> <p>17 MS. AHERN: I'll ask, and you can</p> <p>18 object.</p> <p>19 MR. KLATT: Find out what is in or is</p> <p>20 not in the report.</p> <p>21 MS. AHERN: Let's pick up the</p> <p>22 foundation here.</p> <p>23 BY MS. AHERN:</p> <p>24 Q. Doctor, first of all, you said you did</p> <p>25 the work relating to ovarian cancer pathogenesis</p>
<p style="text-align: center;">Page 207</p> <p>1 granulomatous response. It looks like those are</p> <p>2 the two.</p> <p>3 And then I cite the Mostafa 1985 paper,</p> <p>4 "Foreign body granulomas in normal ovaries."</p> <p>5 I'm double-checking. It looks like in doing</p> <p>6 a word search for granuloma, that's what is</p> <p>7 popping up.</p> <p>8 BY MS. AHERN:</p> <p>9 Q. Okay. Are there any other portions of</p> <p>10 your report that directly address ovarian cancer</p> <p>11 pathogenesis from a pathology standpoint?</p> <p>12 MR. ROTMAN: Objection.</p> <p>13 A. This might be attorney work product</p> <p>14 draft stuff.</p> <p>15 MR. ROTMAN: Do you want to talk to me</p> <p>16 outside where I can understand what you're</p> <p>17 getting at?</p> <p>18 THE WITNESS: Sure. Sure.</p> <p>19 THE VIDEOGRAPHER: Off the record,</p> <p>20 2:50 p.m.</p> <p>21 (A recess was taken.)</p> <p>22 THE VIDEOGRAPHER: Back on the record,</p> <p>23 2:54 p.m.</p> <p>24 BY MS. AHERN:</p> <p>25 Q. Okay. Doctor, I had asked: "Are there</p>	<p style="text-align: center;">Page 209</p> <p>1 from a pathology standpoint; correct?</p> <p>2 A. Yes.</p> <p>3 Q. Was it ever in your report?</p> <p>4 MR. ROTMAN: That's part of the work</p> <p>5 product objection.</p> <p>6 MR. KLATT: We've got to establish the</p> <p>7 facts to know whether there's a basis to assert</p> <p>8 the objection.</p> <p>9 MR. ROTMAN: You can ask the question.</p> <p>10 But in order to answer the question, you're</p> <p>11 invading the domain of what is protected under</p> <p>12 the Federal Rules in terms of the drafting of</p> <p>13 expert reports.</p> <p>14 I will object and instruct her not to</p> <p>15 answer.</p> <p>16 What's in the report, you have. What</p> <p>17 was in drafts of the report, you're not entitled</p> <p>18 to.</p> <p>19 So that's the problem we have.</p> <p>20 MR. KLATT: She's not asking what was</p> <p>21 in the report. She's asking whether it was or</p> <p>22 isn't. So we can establish if there's anything</p> <p>23 to even have a dispute about.</p> <p>24 MR. ROTMAN: You can ask her about what</p> <p>25 is in the report all you want.</p>

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<p>1 MS. AHERN: Well, she's already said 2 there was a section on ovarian cancer 3 pathogenesis from a pathology standpoint in the 4 report, and it was removed; correct?</p> <p>5 MR. TISI: That's not what she 6 testified.</p> <p>7 MS. AHERN: Read back.</p> <p>8 MR. TISI: Why don't we read what she 9 said because she said the answer is:</p> <p>10 "ANSWER: I did the work, but I can't 11 discuss it because of attorney work product."</p> <p>12 MS. AHERN: Okay. Okay.</p> <p>13 MR. TISI: She never said it was in the 14 report.</p> <p>15 MS. AHERN: Thank you.</p> <p>16 MR. TISI: Line 48.</p> <p>17 BY MS. AHERN: 18 Q. When you say you "did the work," did 19 you take any notes on any reading that you did on 20 ovarian cancer pathogenesis? 21 A. So in writing this report, I generally 22 did not take any notes, handwritten notes. It 23 was sort of a living document that I used. 24 Q. Now, earlier, you referred several 25 times to taking notes as you were going through</p>	<p>1 let me rephrase it. 2 As a gynecologic pathologist who was asked 3 to opine on ovarian cancer and talc, did you 4 assume that part of your opinions would be to 5 incorporate your expertise in anatomic pathology 6 and gynecologic pathology? 7 MR. ROTMAN: Wait. Wait. Wait. Wait. 8 Wait. 9 MS. AHERN: I'm only concerned if she 10 understands the question. 11 BY MS. AHERN: 12 Q. Do you understand the question? 13 MR. ROTMAN: No. You have to let me 14 see if I understand the question to see if I'm 15 going to object to it before she's allowed to 16 answer. 17 MS. AHERN: Why don't you make an 18 objection, and we'll move on. 19 MR. TISI: Because he may instruct her 20 not to answer the question. 21 MS. AHERN: This is not -- this is not 22 a question that should invade your privilege. 23 MR. TISI: It involves the discussion 24 between counsel and in the drafting of the 25 reports, what would be in, what would be out,</p>
<p>1 literature. 2 Are all those notes something that became -- 3 on a single document that ultimately became a 4 report? 5 A. It was one document that went through 6 numerous, numerous editing on my part and, of 7 course, suggestions from attorneys at different 8 points. 9 Q. Now, as an anatomic pathologist and as 10 the only pathologist that has been designated by 11 the plaintiffs in this MDL, did you think that it 12 was important to opine on the pathogenesis of 13 ovarian cancer from an anatomic pathology 14 standpoint? 15 MR. ROTMAN: Objection. For what 16 purpose? 17 MS. AHERN: I'm asking her. 18 Q. Can you answer the question? 19 A. First of all, I wasn't aware I was the 20 only pathologist because I didn't have a list of 21 their named experts. 22 I did work on -- I'm not sure how much I can 23 really talk about the whole draft process. 24 MR. ROTMAN: You can't -- 25 Q. So my question was: As an anatomic --</p>	<p>1 what she thought, what she didn't think. You're 2 not entitled to any of that. 3 MR. ROTMAN: So if you can find the 4 question, read the question, and I will object to 5 the question, but you can answer it. 6 A. Okay. So you want me to reread the 7 question? 8 MR. ROTMAN: To yourself. 9 So my question was -- do you see that? 10 THE WITNESS: Yeah. 11 A. Well, I feel as if I did that in my 12 final report. I certainly -- the -- my opinions 13 that are in my final report are certainly within 14 the realm of gynecologic pathology. 15 Q. And can you specifically point to the 16 opinions and the discussions in your report that 17 are within your personal expertise in gynecologic 18 pathology? 19 A. So, again, review of epidemiology is 20 something that physicians do on a regular basis. 21 We're trained to look at epi data. We're trained 22 to practice evidence-based medicine, which has a 23 very similar, if not identical, methodology. 24 So -- and we certainly are trained in 25 inflammation, the immune system, talc and</p>

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<p>1 tissue -- I have a section on talc and tissue -- 2 the epi data. 3 Not -- I don't think any of this report is 4 outside of my -- I know that none of this is 5 outside of my expertise as a gynecologic 6 pathologist. 7 Q. Okay. Doctor, were you retained as an 8 expert epidemiologist in this case? 9 A. I was retained as a gynecologic 10 pathologist. 11 Q. And you are not an epidemiologist; 12 correct? 13 A. I'm not a epidemiologist, but we 14 certainly review epidemiology and critique 15 epidemiology studies on a regular basis in our 16 daily practice. 17 Q. When people ask you what you do for a 18 living, you don't tell them you're an 19 epidemiologist, do you? 20 A. I often have to explain what a 21 pathologist is, so I spend half the time just 22 trying to describe what a pathologist is, so... 23 MR. KLATT: Objection. Nonresponsive. 24 MS. AHERN: Yeah. 25 MR. ROTMAN: She's not done answering</p>	<p>1 Q. You do a full systematic review of the 2 literature, as that term is defined 3 epidemiologically? 4 A. We certainly do when we're doing 5 research, when we're writing papers, but we still 6 do literature searches when we're assigning out 7 cases that are relevant to individual patients. 8 Q. When was the last time you conducted a 9 full systematic review of the literature and a 10 Bradford Hill analysis to opine on causation? 11 A. So, again, this is not something that's 12 completely foreign to me. The legal aspect of it 13 is new to me, but this methodology is not new to 14 me. 15 The last time -- I mean, there was a tobacco 16 case that I worked on, but in my daily practice, 17 again, I'm still looking at epidemiology 18 literature all the time. 19 Q. Well, there is a difference, Doctor, 20 wouldn't you agree, between looking at the 21 epidemiology to inform yourself about a 22 particular issue and doing a systematic review of 23 the literature and a full Bradford Hill analysis 24 to opine on causation? Is there a difference? 25 A. Well, this was a deep dive, so I'll say</p>
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<p>1 your question. She's in the middle of an answer. 2 A. So my point is I'm unlikely to describe 3 myself as an epidemiologist when I'm trying to 4 describe what a pathologist does, but that's the 5 big picture. 6 But the real picture is, on a daily basis, 7 we are evaluating epidemiologic data in the 8 literature. 9 BY MS. AHERN: 10 Q. When was the last time you did a 11 systematic review of the literature for the 12 purpose of opining on causation? 13 A. So we review literature -- 14 Q. You. I'm just talking about you. 15 A. Hold on one second. Let me just review 16 the question. I'm way behind here on my -- 17 Well, I do literature searches all the time 18 and looking -- when I'm looking at cases to 19 figure out causation. 20 I've been involved in one other legal case, 21 but it is -- this was the first medical-legal 22 general causation report. 23 But, again, this is all the same methodology 24 that we use in evidence-based medicine and our 25 practice.</p>	<p>1 I was aware of the literature on talcum powder 2 and ovarian cancer before I became involved in 3 this litigation. 4 I will say, you know, it wasn't until they 5 asked me to form my opinion on this that I did a 6 deep dive on the literature again on this 7 particular issue. 8 Again, I've certainly done extensive 9 literature reviews before to, you know -- in 10 research and in practice. 11 Q. But nothing like this? 12 A. It's very similar. 13 MR. ROTMAN: Objection. 14 A. The methodology is very similar to 15 this. It's identical. 16 Q. Doctor, can you point me to -- take a 17 look at Exhibit 2, your CV. 18 Can you point me to something in your CV 19 that demonstrates some specialized knowledge or 20 expertise in epidemiology? A course, a class 21 you've taught? A paper that you've published? A 22 case-control study you've been involved in? 23 Anything that would indicate that you have 24 specialized expertise in epidemiology? 25 A. It's part of our medical training as</p>

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<p>1 part of evidence-based medicine. 2 I'm trying to find my CV. I'm not sure I 3 have it in front of me. Maybe it's under here. 4 Well, you're sitting in -- I mean, all of these 5 involved epidemiology research. 6 MR. ROTMAN: All of what? 7 A. I'm sorry. All of these research 8 projects start with -- the pathology publications 9 start with looking at the literature of 10 epidemiology. 11 Q. Which ones are you pointing to -- 12 sorry. Let's look at the peer-reviewed 13 publications. 14 Is that what you're talking about? 15 A. Yes. Sorry. 16 Q. So the first publication is Narasimhan, 17 "Temperature Induced Interstrand Crosslinks in 18 Cisplatin-DNA Adducts Detected by Electrophoresis 19 and UV Spectrophotometer." 20 That's not an epi study, is it? 21 A. Some of these were biology. The one 22 that comes to mind when I'm looking at this list 23 is the "Yersinia pestis and the plague." That 24 was a review article. That was around -- that 25 was after the 2001 mailings of the pattern</p>	<p>1 So that was sort of more the review on that. 2 Q. Who is S.M. Rollins? 3 A. That's my ex-husband. 4 Q. What is his specialty? 5 A. He's a microbiologist. 6 Q. What about Ryan? 7 A. He is an infectious disease physician. 8 Q. Okay. What portion of "Yersinia pestis 9 and the plague" did you draft or did you 10 contribute? 11 A. I drafted the entire -- I was the lead 12 author, and I -- the primary author, and I 13 drafted that report. 14 Q. Okay. So if we go in there, we're 15 going to find you used statistical methods or 16 analysis in any way to weigh the evidence and 17 conduct a systematic review? 18 A. It's definitely a review article. Off 19 the top of my head, I don't know if I did a 20 statistical analysis, but... 21 Q. Would you describe it as more of a 22 narrative review of the literature? 23 A. A review of the literature. I don't 24 know about the word "narrative," but review. 25 Q. What about the Grundy paper,</p>
<p style="text-align: center;">Page 219</p> <p>1 substance. And so the literature was very 2 interested in Yersinia pestis at the time, and so 3 I did a review article on that. 4 Q. Was that a systematic review and a 5 Bradford Hill analysis? 6 A. The Bradford Hill analysis is part of 7 evidence-based medicine when you're coming to a 8 conclusion. So -- 9 Q. This isn't a case-control study or a 10 prospective cohort study -- 11 MR. ROTMAN: You're not allowing her to 12 finish her answer. 13 Q. -- or epidemiology study, is it? 14 A. But my general causation opinion is 15 very similar to a review article on causation. 16 It's a review of the epi data and mechanisms. 17 Q. Did you do a full review of the epi 18 data and mechanisms on Yersinian plague? 19 It's kind of a done deal; right? We already 20 know that; isn't that right? 21 A. Well, you're still looking at -- you're 22 still looking at data. The question is -- the 23 question was at the time: Can Yersinia pestis be 24 a dangerous weapon of destruction or 25 terrorist-type agent?</p>	<p style="text-align: center;">Page 221</p> <p>1 "Specificity of tRNA-mRNA Interactions in 2 Bacillus substillis tyrS Antitermination"? 3 Is that an epi study? 4 A. No. 5 Q. What about the Rollins paper, 6 "Diagnostic yield of muscle biopsy in patients 7 with clinical evidence of mitochondrial 8 cytopathy"? 9 Is that an epidemiologic article? 10 A. No. That's not an epidemiology 11 article, but we -- 12 Q. Sorry? 13 A. It's getting late in the day. 14 MR. TISI: Do you need some water? 15 THE WITNESS: Sure. 16 A. But it's interesting that it actually 17 did involve electron microscopy. And when we do 18 muscle biopsies for mitochondrial cytopathy, we 19 use electron microscopy anyway, regularly. 20 MR. KLATT: Objection. Nonresponsive. 21 Q. And what about the Rollins 22 "Autoimplants and serous borderline tumors of the 23 ovary: A clinicopathologic study of 30 cases and 24 a process to be distinguished from serous 25 adenocarcinoma"?</p>

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<p>1        Was that a systematic review of the 2 literature, or an epidemiologic study? 3        A. There's definitely review of literature 4 as part of that study because the question arises 5 with autoimplants, sometimes they're misdiagnosed 6 as invasive serous. 7        So there is definitely literature review for 8 that study. 9        Q. This would be described as you have it 10 in the title, this is a clinicopathologic study? 11      A. Correct. 12      Q. So you were looking at this as a 13 pathologist; correct? 14      A. Well, I'm looking at -- I mean, some of 15 these were before I was -- the first couple are 16 before I was an M.D., but all of the subsequent 17 ones I'm looking at as a pathologist. 18      Q. What about the Chan study, 19 "Clinicopathologic Correlation of Fetal Vessel 20 Thrombosis in Mono- and Dichorionic Twin 21 Placentas"? 22      Is that an epidemiologic study? 23      A. That's a clinicopathologic correlation. 24      Q. And then the publication with Jonathan 25 Hecht, "Endometrial Interepithelial Neoplasia,"</p>	<p>1        are degreed epidemiologists who have been 2 designated on behalf of plaintiffs to look at 3 these issues; correct? 4        A. I'm aware of that now. I didn't know 5 who their list was before I submitted my report. 6        Q. You've never published -- as we just 7 looked through here -- an epidemiologic study, a 8 case-control study, or a cohort study? 9        A. I have not published; but, again, that 10 doesn't -- I mean, it doesn't mean I haven't done 11 them. It's just that -- 12      Q. Have you done them? 13      A. They haven't been published. Well, 14 again, literature reviews of epidemiology is part 15 of our regular practice. 16      Q. I'm asking about, like, actual study 17 designs. 18      Have you conducted a case-control or a 19 cohort study? 20      A. Not of an epi -- 21      Q. Okay. 22      A. -- specific design. 23      Q. Have you ever taught an epidemiology 24 course? 25      A. No.</p>
<p style="text-align: center;">Page 223</p> <p>1        is that an epidemiology study? 2        A. That was a review of a new terminology 3 in endometrial precursor lesions. So that was a 4 pathologic -- an anatomic pathology article. 5        Q. And then you have the one with Haspel, 6 which is "Successful Implementation of a 7 Longitudinal, Integrated Pathology Curriculum 8 During the Third Year of Medical School"? 9        A. That was a medical-education-type 10 article. 11      Q. Okay. And do you have any proceedings 12 of meetings, poster presentations, that were from 13 a case-control or a cohort study that you 14 conducted? 15      A. Let me look. I don't believe these 16 poster presentations were case -- well, I mean, 17 case-control or cohort epi-type studies. 18      Q. Okay. And, Doctor, to be fair, you 19 don't have a degree in epidemiology; correct? 20      A. I do not have a degree. But, again, 21 it's -- epidemiology is a very big part of 22 evidence-based medicine and what we practice as 23 M.D.s. 24      MR. KLATT: Objection. Nonresponsive. 25      Q. And, Doctor, you understand that there</p>	<p style="text-align: center;">Page 225</p> <p>1        Q. Do you have any grant funding to 2 conduct epidemiologic observational studies? 3        A. No. 4        Q. Have you ever given any lectures or 5 presentations specifically on epidemiology 6 methodologies? 7        A. That's possible. I'm trying to think. 8 It's been a long time. Medical school through 9 residency, fellowship, not that I can think of 10 off the top of my head. 11      Q. Okay. And have you ever designed a 12 clinical trial? 13      A. I have not designed a clinical trial. 14      Q. Have you designed a case-control study? 15      A. I have not designed a case-control 16 study. 17      Q. Have you designed a cohort study? 18      A. I have not designed a cohort study; 19 but, again, these are -- we can critically 20 evaluate. Just because I haven't designed one 21 doesn't mean I can't critically evaluate 22 case-control studies or cohort studies. 23      Q. Doctor, you haven't conducted a 24 meta-analysis or a pooled analysis to evaluate 25 potential risk factors for any disease, have you?</p>

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<p>1 A. No, I haven't. 2 Q. Are you qualified to conduct a 3 meta-analysis or a pooled analysis? 4 A. I'm -- I'm sure I could develop one. 5 Q. As we sit here today, are you qualified 6 to conduct a meta-analysis or a pooled analysis? 7 A. If it was sort of a joint venture, I'm 8 sure; but, again, that doesn't mean that I can't 9 critically evaluate them, because that's what I 10 do on a daily basis. 11 Q. Have you authored any paper or 12 conducted a study -- well, have you authored any 13 paper on the methods of causal interpretation? 14 A. Have I authored a paper on the methods 15 of causal interpretation? 16 I don't believe I've authored. It would be 17 on my list. 18 Q. Okay. Doctor, I should have asked you 19 this when it was in front of you: Do you have a 20 copy of that one-page additional materials? 21 A. Probably. Let's see. 22 Q. Thank you. Maybe I have. Maybe I have 23 it too. 24 A. Exhibit 17? 25 Q. Yes. Yes.</p>	<p>1 asbestos in it, that would certainly add to the 2 plausibility of causation. 3 Q. If there was not asbestos in talcum 4 powder products and there was not fragrance in 5 talcum powder products and you were just left 6 with the pharmaceutical-grade talc, what would 7 your biologic plausibility argument be? 8 MR. ROTMAN: Objection. 9 Q. In other words, what is your mechanism 10 by which pharmaceutical-grade talc would cause 11 ovarian cancer? 12 MR. ROTMAN: Objection. Are you asking 13 about causation or about biological plausibility? 14 MS. AHERN: I'm asking -- 15 MR. ROTMAN: You mixed them. 16 MS. AHERN: -- about her mechanism. 17 BY MS. AHERN: 18 Q. What is your mechanism by which 19 pharmaceutical-grade talc would cause ovarian 20 cancer? 21 A. So there are -- again, most of the 22 studies are dealing with talc powder products. 23 If we were to say that all that was in there is 24 pharmaceutical -- it's completely hypothetical 25 because I don't know what's in there -- I still</p>
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<p>1 You received a copy of the Longo 2 supplemental report; correct? 3 A. I did. Yes. 4 Q. And it's, what, 404 pages? 5 A. That's possible. I don't think I 6 looked. 7 Q. That was my next question: Did you 8 review it? 9 A. I did review it. I did skim a lot of 10 it because, again, it was additional information 11 that was nice to have, but it was after my 12 report. 13 And, again, my general causation opinion is 14 not dependent on asbestos being in the product. 15 My general causation opinion is based on whatever 16 is in the bottle. So it was interesting 17 information to have. 18 Q. So your opinions here, it doesn't 19 matter for your opinions whether or not there's 20 asbestos in talcum powder products; is that your 21 testimony? 22 A. What I'm saying is my opinion is based 23 on whatever is in the talcum powder product's 24 bottle. Now, it's up to the jury to decide if 25 there's asbestos in it. However, if there is</p>	<p>1 think the mechanisms would be similar where, you 2 know, there's evidence that talc can cause 3 inflammation, and we know that inflammation is a 4 cause of cancer. 5 And so I -- and there's also, you know, 6 Dr. Cramer talked about anti-MUC-1 antibodies, so 7 there's an immune -- plausible immune mechanism, 8 so I think all of those are still on the table 9 and the hypothetical situation that it's only 10 pharmaceutical-grade talc in that bottle. 11 But, again, I -- I'm not opining about what 12 is in the bottle; I'm just opining about that -- 13 whatever that product is in that bottle causing 14 ovarian cancer. 15 Q. Okay. Let's take a look at your expert 16 report again, Exhibit 14, if you will. 17 Just let me know when you've got it. 18 A. Yeah. 19 Q. Okay. Doctor, does Exhibit 14, your 20 November 15, 2018, expert report, contain all of 21 the opinions that you intend to offer as a 22 witness in this matter? 23 A. I wouldn't box myself in that way. 24 There might be questions that I'm asked here 25 today or in trial that aren't necessarily in my</p>

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<p>1 report. 2 Q. Okay. But the opinions that you intend 3 to offer, absent somebody asking you to offer 4 other opinions, are all outlined or contained 5 within Exhibit 14, your report; is that correct? 6 A. Again, I wouldn't want to say "all." I 7 wouldn't want to limit myself. There's always 8 the possibility that something else will come up, 9 and I even have a thing that additional 10 information may come up. 11 Q. Okay. As we sit here today, do you 12 understand that this is our opportunity to ask 13 you about the opinions in your report, and we 14 have the day to do it? 15 Do you understand that? 16 A. I understand. 17 Q. Okay. So to the extent that you think 18 you're going to offer additional opinions or 19 different opinions, we need to know that today. 20 I understand that if something comes up two 21 weeks from now and it's additional information, 22 you might supplement your report. 23 But as of today, as we sit here today, is 24 this report an accurate reflection of the 25 opinions that you have formed and that you intend</p>	<p>1 probably have within them all the references to 2 your report. Other than those and what you 3 brought with you today, is there anything else 4 related to your work on your report that you have 5 in your possession that you haven't been able to 6 bring with you today? 7 A. Not that I'm aware of. I've tried to 8 be very complete in my list of what I reviewed. 9 It's possible -- again, it's possible there are a 10 couple of things that might have been left off, 11 but I tried to be as complete as possible. 12 Q. Okay. And you mentioned earlier you 13 had done some work on the pathogenesis of ovarian 14 cancer. 15 Did you have any articles or publications 16 that are related to that work that are not 17 referenced in your report? 18 A. I believe they should be in the list. 19 They should be included in the list that you 20 have. 21 Q. The one from -- your initial report? 22 A. Taken all together. Taken all 23 together. So that, probably, is more -- the 24 January 4th one would probably be some of those. 25 And then I can't remember what's on that one</p>
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<p>1 to offer in this case? 2 A. I would say it's an accurate reflection 3 of the opinions I have formed with the exception 4 of anything that might be asked that is not in 5 the report; but yes. 6 Q. All right. All right. 7 And as we sit here today, is your report 8 complete? 9 A. Well, it's signed and turned in, so -- 10 Q. Do you, as the expert designated in 11 this case, Sarah Kane, do you consider your 12 report to be complete as we sit here today? 13 A. Yes. 14 MR. ROTMAN: Off the record. 15 (Discussion off the record.) 16 THE VIDEOGRAPHER: Off the record, 17 3:24 p.m. 18 (A recess was taken.) 19 THE VIDEOGRAPHER: Here begins Media 20 No. 5 in today's deposition of Sarah Kane, M.D. 21 Back on the record, 3:39 p.m. 22 BY MS. AHERN: 23 Q. Okay. Dr. Kane, we were talking about 24 your report. Just some basic housekeeping first. 25 We have the four boxes back here which</p>	<p>1 that you just got, but if there's a couple on 2 there. 3 But I would think if they weren't cited in 4 the report, the majority of those should be in 5 the January 4th list. 6 Q. Okay. And those would pertain to the 7 various histologic categorizations of ovarian 8 cancer; what is known about etiology. 9 Is that kind of the gist of the information 10 that you researched? 11 A. Yes. Yes. That was certainly part of 12 it. 13 Q. And were there other parts to that? 14 THE WITNESS: Is that -- I don't know 15 if -- 16 MR. ROTMAN: Yeah. You can say what 17 work you did. 18 A. There was -- so a good bit of it was 19 sort of background information on the pathologic 20 diagnosis of ovarian cancer and different, as you 21 said, different subtypes. 22 There was -- I'm trying to remember -- it 23 was so long ago -- what some of the -- I believe 24 there was a little bit more on inflammation, but 25 I can't say for sure.</p>

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<p>1 BY MS. AHERN:</p> <p>2 Q. And would that have been just related 3 to ovarian cancer pathogenesis?</p> <p>4 A. Yes. Yes.</p> <p>5 Q. And you think that all of the 6 publications that you found, identified, reviewed 7 in relation to that work are identified in one of 8 the lists or across several lists?</p> <p>9 A. I'm hoping that across all of the 10 lists, that encompasses the vast majority, if not 11 all. But let's just keep it at vast majority.</p> <p>12 And, of course, you know, I'm a gynecologic 13 pathologist, so I read tons of other stuff that, 14 you know, is just my background knowledge that 15 I'm not going to put on these lists. So I can't 16 say it's all-inclusive; but, again, I tried.</p> <p>17 Q. Understood. Understood.</p> <p>18 And you've now seen at least one report from 19 Dr. Robert Kurman; correct?</p> <p>20 A. That's correct. That was an individual 21 causation report, though. So...</p> <p>22 Q. And he had a very large background 23 section on ovarian cancer pathogenesis; correct?</p> <p>24 A. To be honest with you, I sort of 25 skimmed it, but I do remember seeing a section on</p>	<p>1 Exhibit 14, your expert report, are they solely 2 the product of your own work?</p> <p>3 A. Yes. I wrote the report. Certainly, 4 again, there were drafts that went back and 5 forth. There may have been suggestions from 6 attorneys where language was -- that I accepted 7 into my report; but yes.</p> <p>8 Q. Okay. You didn't borrow language from 9 other experts or from other publications and then 10 not quote that in your report?</p> <p>11 A. I certainly tried not to. No. I 12 certainly cited anything that I -- I tried to 13 cite everything that I referenced --</p> <p>14 Q. Okay.</p> <p>15 A. -- to the best of my ability.</p> <p>16 You know, again, I was taking the notes as I 17 wrote, so it's plausible there might be 18 something, but I was very cognizant of trying not 19 to -- trying to cite everything that I was 20 referencing.</p> <p>21 Q. And in reaching your opinions, was it 22 important to you that you review the data in a 23 fair and objective way?</p> <p>24 A. Yes. I think it's always important to 25 review data in a fair and objective way.</p>
<p style="text-align: center;">Page 235</p> <p>1 that. Yes.</p> <p>2 Q. Okay. Did you skim the section that 3 was case-specific?</p> <p>4 A. No. Mostly the background since I 5 already know that stuff.</p> <p>6 Q. Okay. And is the stuff that was in his 7 background section similar to the research that 8 you did?</p> <p>9 A. I would say yes. If I am remembering 10 accurately, it was similar. I wouldn't say 11 identical, but similar.</p> <p>12 Q. Okay. And did anyone other than your 13 attorneys assist you in preparing the report?</p> <p>14 A. No.</p> <p>15 Q. And you said earlier, I think, that you 16 didn't consult with any of the other experts in 17 the MDL litigation in forming your opinions or 18 preparing your report?</p> <p>19 A. That's correct.</p> <p>20 Q. And you didn't review any draft reports 21 from any other experts in this litigation?</p> <p>22 A. No. The only time I saw their reports 23 was after we had all turned them in to the court.</p> <p>24 Q. Okay. And are all of the words, the 25 ideas, the analysis that's contained in</p>	<p style="text-align: center;">Page 237</p> <p>1 Q. I know. It's kind of a basic question. 2 When you were doing your literature reviews 3 and searches, were you looking both for papers or 4 data that supported talc and ovarian cancer 5 connection as well as for data and literature 6 that did not or that -- well, that did not 7 support?</p> <p>8 A. When I was doing my literature search, 9 I was looking for any data that spoke to talcum 10 powder products and ovarian cancer. I was really 11 trying to cast as wide a net as possible to get 12 as much data as I could.</p> <p>13 Now, certainly, there are limitations when 14 you're doing searches. It's possible there are 15 studies that I missed; but when I was retrieving 16 studies, reading them, I would also reference 17 their references as a sort of cross-check. So I 18 tried to be as complete as I could.</p> <p>19 Q. So when you were reading someone else's 20 work and they referenced an article as the basis 21 for synthesis or the statement in their paper, 22 did you then go and review the underlying 23 reference as well?</p> <p>24 A. Yes. I pulled up those references.</p> <p>25 Q. Okay. And you reviewed those as well?</p>

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<p>1        A. Yes.</p> <p>2        Q. Okay. And you mentioned on Page 4 of</p> <p>3        your report that your interest in talc and</p> <p>4        ovarian cancer began during your training, your</p> <p>5        fellowship training, at Mass General; is that</p> <p>6        right?</p> <p>7        A. I became aware of it. I mean, both</p> <p>8        Dr. Scully and Dr. Bell were still there at my</p> <p>9        time of training, and Dr. Scully was a coauthor</p> <p>10      on Cramer's first 1982 paper.</p> <p>11      And then Dr. Bell was a coauthor in one of</p> <p>12      the subsequent -- I think his 1992 paper with</p> <p>13      Harlow.</p> <p>14      So I was certainly aware of literature on</p> <p>15      talcum powder and ovarian cancer.</p> <p>16      Q. And neither one of them published</p> <p>17      anything else on talc; is that correct?</p> <p>18      A. I believe those were the only two that</p> <p>19      they were on. That's correct.</p> <p>20      Q. And did you understand that the role</p> <p>21      that Dr. Scully played on Dr. Cramer's first</p> <p>22      publication was simply that of pathologist and</p> <p>23      determining or confirming the diagnosis of the</p> <p>24      samples that were being studied?</p> <p>25      A. I was aware that he did a pathologic</p>	<p>1        I know we talked about the Nurses' Health Study.</p> <p>2        That's funny, though, I actually did talk --</p> <p>3        I saw Jonathan last night, so it's kind of funny</p> <p>4        timing. But anyway...</p> <p>5        Q. Have you talked to Dr. Hecht since</p> <p>6        then, since you first discussed with him the</p> <p>7        Nurses' Health Study?</p> <p>8        Have you spoken with him on talc and ovarian</p> <p>9        cancer?</p> <p>10      A. Yes. I saw him last night. We went</p> <p>11      out for a drink.</p> <p>12      Q. Did he give you any opinions on what he</p> <p>13      thought about talc and ovarian cancer?</p> <p>14      A. He told me that he had met with defense</p> <p>15      counsel at one point; did not want to do medical</p> <p>16      expert witness work but did a brief sort of</p> <p>17      intro, I guess, overview for the defense.</p> <p>18      Q. Did he tell you what his personal or</p> <p>19      his professional opinion was on whether or not</p> <p>20      talc causes ovarian cancer?</p> <p>21      A. Yes. He thought that -- so I'll say in</p> <p>22      my report, I did not spend a lot of time on</p> <p>23      migration because in the gynecologic world, it's</p> <p>24      widely accepted that migration happens. He told</p> <p>25      me that he specifically told the defense counsel</p>
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<p>1        review of the case.</p> <p>2        Q. Okay. Did you ever have an opportunity</p> <p>3        to talk to Dr. Scully about talc and ovarian</p> <p>4        cancer?</p> <p>5        A. I believe my conversations were -- my</p> <p>6        memory is -- this is 20 years ago now -- it's</p> <p>7        possible, but probably with Dr. Bell, more. I</p> <p>8        interacted more with Dr. Bell than Dr. Scully.</p> <p>9        Dr. Scully was semiretired at the time. He</p> <p>10      would come in for half the day, but that was</p> <p>11      usually when I was with other attendings. But I</p> <p>12      did spend a significant time with Dr. Bell, and I</p> <p>13      do remember being aware of that literature.</p> <p>14      Now, if you're going to ask me the specific</p> <p>15      conversation, I probably can't prompt that at the</p> <p>16      moment.</p> <p>17      I was also, when I was at Beth Israel</p> <p>18      Deaconess, my colleague Jonathan Hecht is there.</p> <p>19      And I was aware he was doing work on the Nurses'</p> <p>20      Health Study.</p> <p>21      We didn't -- I can't remember if we really</p> <p>22      talked about talc at that point because the Gates</p> <p>23      2010 paper that he was doing, talc was a very</p> <p>24      small -- it was almost, like, a side comment in</p> <p>25      that report. But I think we had talked about --</p>	<p>1        he met with not to use migration because it's</p> <p>2        widely accepted that it occurs.</p> <p>3        We did talk about the Nurses' Health paper.</p> <p>4        He said that the data set was very small, it was</p> <p>5        very difficult with classification, and that</p> <p>6        that -- there just really wasn't a lot of data in</p> <p>7        that 2010 study.</p> <p>8        And he thinks that it is plausible for</p> <p>9        talcum powder to cause ovarian cancer.</p> <p>10      Q. Have you spoken to any other</p> <p>11      pathologist or colleagues about talc and ovarian</p> <p>12      cancer?</p> <p>13      A. I have talked to my coworkers about it</p> <p>14      because -- as a conflict-of-interest notification</p> <p>15      for our group and for our hospital, Partners</p> <p>16      Healthcare, and I discussed my findings with my</p> <p>17      partners.</p> <p>18      And I've also talked about it at</p> <p>19      multidisciplinary conferences; recently at, for</p> <p>20      example, at a thoracic conference. There were</p> <p>21      gyn oncs there and radiologists and rad onc</p> <p>22      people there.</p> <p>23      Q. And you talked to them specifically</p> <p>24      about talc and ovarian cancer?</p> <p>25      A. So I told them about my work on it and</p>

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<p>1 the research that I had done, and I was asking 2 them -- it was a thoracic conference, so I was 3 curious if any of them had asked any of their 4 mesothelioma patients that didn't have 5 nonasbestos exposure if they've ever asked them 6 if they'd had talc exposure. 7 And they said no, they hadn't really done 8 it, they hadn't thought about it, but maybe it 9 was something that they should be asking. 10 Q. And, by the way, what were the 11 circumstances under which you and Dr. Hecht had 12 dinner the other night? 13 A. His birthday is coming up. We're still 14 friends, so it was one of these -- I actually 15 stayed in a hotel last night because it took me 16 an hour and a half to drive from Topsfield 17 yesterday morning, and I didn't want to be 18 worried about traffic. So I decided to stay in a 19 hotel last night. His birthday is coming up, so 20 I said, "Let's just grab a drink." 21 Q. You mentioned while you were at Mass 22 General, the fellowship director for your program 23 was Robert Young; correct? 24 A. Yes. 25 Q. Is he someone that you look up to as a</p>	<p>1 Dr. Scully retired; is that right? 2 A. Yes. He inherited his consult service. 3 So it's a separate service from our regular 4 clinical work. So it's pathologists from all 5 over the country or even world that have 6 difficult cases, they will send as a specific 7 private consult to -- it was Dr. Scully, and now 8 it's Dr. Young. 9 Q. Okay. When you were first contacted by 10 the plaintiffs' counsel back in 2017, what were 11 your opinions regarding talc and ovarian cancer 12 at that point? 13 A. First contacted? When I was first 14 contacted, I was aware of the literature, 15 certainly. I hadn't come to a strong opinion one 16 way or the other. In fact, I'd probably say I 17 was aware that the epi data had been relatively 18 consistent. That was kind of all I knew about it 19 until I did my sort of deep dive into the 20 literature for my general causation opinion. 21 Q. So as a pathologist, you never had a 22 particular interest in pursuing additional 23 research in the area -- 24 MR. ROTMAN: Objection. 25 Q. -- of talc and ovarian cancer?</p>
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<p>1 pathologist? 2 A. Yes. He's very well-respected. 3 Q. By the way, who do you send second 4 opinion consults to when you have a difficult 5 case? 6 A. We have a relationship with Mass 7 General, so I'll occasionally send -- if I need 8 another set of eyes on, I'll send it to either -- 9 it's sort of their gyn pathology group in 10 general, so it might be Dr. Young. It might be 11 Esther Oliva. Those are the two that I would say 12 most frequently would receive any consults from 13 our group for gyn path. 14 Q. Have you ever spoken with Dr. Young 15 about talc and ovarian cancer? 16 A. It's possible. I haven't recently. He 17 and I aren't in regular communication, so I 18 certainly wouldn't have talked to him -- I don't 19 know if I've talked to him since starting this. 20 It's more of a professional-type 21 relationship, so I don't know if it would have 22 come up recently. But it's possible in training, 23 but I don't remember specifically. 24 Q. And Robin Young inherited all of 25 Dr. Scully's case files in his office when</p>	<p>1 A. Well, there's certainly a lot of things 2 to study in gynecologic pathology. And so I 3 hadn't decided to take that -- to do that study 4 at the time that I was contacted by counsel. 5 That's not to say I never would have or I never 6 would have thought about it, but I hadn't at the 7 time. 8 Q. Okay. In your report on Page 4, you 9 say that you've maintained a professional 10 interest -- "since your fellowship, you've 11 maintained a professional interest and have 12 continued to monitor developments in the science 13 regarding talcum powder exposure and ovarian 14 cancer, and it has been the subject of 15 professional discussions predating the 16 litigation." 17 So what sort of professional discussions 18 about talc and ovarian cancer did you have before 19 the plaintiffs retained you? 20 A. So, again, I was aware of the 21 literature. And I knew -- I saw some of the 22 newer epi data come out. I had had conversations 23 with Dr. Bell that I remember specifically; 24 again, with Jonathan. I knew he was working on 25 that Nurses' Health. We certainly talked about</p>

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<p>1 that study at some point. 2 But, you know, I was certainly aware of the 3 literature as it came out. 4 Q. And you call it a "professional 5 interest." 6 Did you take -- other than just reviewing 7 the literature, did you do anything 8 professionally to either advance your knowledge 9 or other people's knowledge about this potential 10 association? 11 A. Not -- I mean, not at the time. I 12 think "professional interest" in my mind, you 13 know, means being aware of what's going on in the 14 literature. Again, that doesn't necessarily mean 15 an in-depth review of everything but being 16 generally aware of it. 17 Q. Would you say that since you first 18 learned about this in your fellowship and were 19 interested in the topic, did it influence the way 20 you looked at gynecologic cases as a professional 21 pathologist? 22 A. Yeah. It's not really routine practice 23 to use polarized light microscopy in gynecologic 24 pathology. It's just -- we use it more commonly 25 for breast cases, so...</p>	<p>1 in the report. 2 Q. Okay. And the first opinion is that 3 talc can migrate to the ovaries through the 4 genital tract through the lymphatic system and 5 through inhalation. 6 Is that an accurate summary of your first 7 opinion or set of opinions? 8 (reading from document) 9 A. Yes. The talcum powder products can 10 reach the ovaries; that they can be transported 11 through the lymphatic system; and there is 12 evidence that it can be inhaled as well with 13 transport to the ovaries. 14 Q. And the second opinion in the case or 15 second set of opinions is that talc causes 16 chronic inflammation in the ovaries, causes 17 increased oxidative stress in the ovaries, and 18 causes immunosuppression. 19 Is that an accurate summary of your 20 mechanism? 21 A. Well, if you're going to read it word 22 for word, it's "Once reaching the ovaries, talcum 23 powder products can cause chronic inflammation, 24 can increase oxidative stress, and can reduce 25 immune response. These are biologically</p>
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<p>1 And also, you know, even if we found 2 birefringent particles and granulomas or -- in 3 the tissue, it wouldn't necessarily mean that 4 they're talc unless you do subsequent studies. 5 So I wouldn't say it changed my daily 6 practice in diagnosing tumors. 7 Q. Okay. Doctor, if you can turn to 8 Page 4 and 5 of your report. 9 Is this where you set out a summary of your 10 opinions? 11 A. Yes. This is. 12 Q. Under Heading 2, Page 4, "General 13 causation opinions." 14 A. Okay. 15 Q. And you list, it looks like, five 16 specific opinions; is that correct? 17 A. I see where you are. Yes. 18 Q. And are those -- again, are those all 19 the opinions that you have that you intend to 20 offer in this case? 21 MR. ROTMAN: Objection. 22 A. Same answer as before. Again, there 23 might be something that comes up today or at 24 trial that I'm asked that I, you know, didn't put 25 in this report. But I tried to be as -- complete</p>	<p>1 plausible and likely mechanisms for ovarian 2 cancer development and progression." 3 Q. Okay. When you say "reduce the immune 4 response," is that essentially discussing, like, 5 an immunosuppressive effect? 6 A. That's referencing the MUC-1 antibody 7 paper that Cramer published in 2005. 8 Q. Are you aware that Dr. Cramer himself 9 has disclaimed that theory as a "hypothesis 10 that's not ready for prime time"? I believe 11 those were his words, "prime time." 12 A. I don't know where you saw those words. 13 Q. His testimony in the litigation. 14 A. Okay. I don't believe I saw his 15 testimony in the litigation. But, again, it's 16 not -- I'm not seeing it as something that needs 17 to be proven. I'm looking at it as a 18 plausibility that, you know, it's a plausible 19 mechanism. If it's not proven, it doesn't really 20 change the fact that it's plausible. 21 Q. So are you building -- so is your 22 plausibility opinion independent of whether or 23 not the basis for that opinion is proven? 24 MR. ROTMAN: Objection. 25 Q. In other words, are you -- do you have</p>

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<p>1 a plausibility opinion that's based on a bunch of      2 other potential or plausible mechanisms?</p> <p>3 MR. ROTMAN: Objection.</p> <p>4 A. Right.</p> <p>5 MR. ROTMAN: I just objected, but you      6 can answer. If you can understand the question,      7 you can answer it.</p> <p>8 A. Well, I think -- I think they're all      9 somewhat interrelated.</p> <p>10 I think there's the chronic inflammation.      11 There's the immune response. Those are plausible      12 mechanisms for ovarian cancer.</p> <p>13 And the Bradford Hill guidelines, you don't      14 have to prove -- prove mechanism in order to have      15 causation. We have plenty of -- again, plenty of      16 examples of that in prior diseases, like smoking      17 and lung cancer. And even certain drugs, they      18 don't know the mechanism of action, very common      19 drugs like lithium, for example, or metformin.</p> <p>20 So you don't need to prove mechanism in      21 order for it to be an important part of a      22 causation because it's part of the plausibility      23 component.</p> <p>24 Q. Do any of the bases on which you -- any      25 of the bases that you use to support plausibility</p>	<p>1 reaching the ovaries.</p> <p>2 So -- and, again, it's widely accepted in      3 the gynecologic community that migration occurs.      4 In fact, endometriosis, we really -- the evidence      5 is that endometriosis is caused by retrograde      6 menstruation of endometrium.</p> <p>7 So there's a substantial amount of evidence      8 and widely accepted that migration occurs.</p> <p>9 And I'm aware of studies that didn't find      10 migration, but I think, you know, those few      11 negative studies don't cancel out the positive      12 studies.</p> <p>13 And, you know, certainly, looking for      14 migrated particles is very difficult. You know,      15 again, we're talking about dose. How much do you      16 inject to get there?</p> <p>17 And so I think the positive studies are      18 compelling, and it's widely accepted that      19 migration occurs.</p> <p>20 (Article entitled "Presence of      21 Talc in Pelvic Lymph Nodes of a Woman with      22 Ovarian Cancer and Long-Term Genital      23 Exposure to Cosmetic Talc" marked Exhibit      24 19.)</p>
<p style="text-align: center;">Page 251</p> <p>1 for talc and ovarian cancer, do any of them have      2 to be proven or established?</p> <p>3 MR. ROTMAN: Objection.</p> <p>4 A. I think it's important to have evidence      5 to support it. There may be evidence that      6 refutes it as well, but you're sort of looking      7 at -- you're balancing the weight of it.</p> <p>8 And the plausibility, a plausible mechanism,      9 now, is that always going to be probable or      10 definite? No. It's plausible.</p> <p>11 In this case, I think it's a compelling      12 mechanism, chronic inflammation, because, again,      13 we know that talcum powder can reach the ovaries,      14 and we know that it can cause chronic      15 inflammation, and we know chronic inflammation is      16 implicated in cancer.</p> <p>17 So I think it's a high degree of      18 plausibility in that case.</p> <p>19 Q. So when you mention that you know that      20 talc can reach the ovaries, are you referring to,      21 for example, the Heller study?</p> <p>22 A. So Heller found talc in women's      23 ovaries. Yes. Cramer found talc in pelvic lymph      24 nodes. We have other animal and human studies of      25 talc or particulates similar in size to talc</p>	<p style="text-align: center;">Page 253</p> <p>1 BY MS. AHERN:</p> <p>2 Q. Doctor, I'm handing you what's been      3 marked as Exhibit 19 to your deposition.</p> <p>4 A. Okay.</p> <p>5 MR. TISI: Thank you.</p> <p>6 MS. AHERN: You're welcome.</p> <p>7 Q. Exhibit 19 is an article drafted by      8 Dr. Dan Cramer, the "Presence of talc in pelvic      9 lymph nodes of a woman with ovarian cancer and      10 long-term genital exposure to cosmetic talc."</p> <p>11 Is this a paper that you were referring to a      12 few minutes ago?</p> <p>13 A. The 2005, yes.</p> <p>14 Q. This is 2007.</p> <p>15 A. I'm sorry. Did I say 2005? Yes. This      16 is the paper, anyway.</p> <p>17 Q. And the authors are Dan Cramer and Bill      18 Welch, Ross Berkowitz, and John Godleski.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And three of those individuals have      22 been disclosed as plaintiffs' experts in the talc      23 litigation.</p> <p>24 Were you aware of that?</p> <p>25 A. I was not aware of Bill Welch. I knew</p>

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<p>1 after -- at some point, I was aware that      2 Dr. Cramer and Dr. Godleski was. I don't believe      3 I was aware of that at the beginning of my      4 research, but I became aware of that. Yes.      5 Q. Okay. Are you aware that Dr. Welch has      6 been designated in maybe three cases and given      7 testimony in those cases?      8 A. Again, I was not aware that Bill Welch      9 had been retained.      10 Q. Are you aware that Dr. Welch has run      11 the pathology portion of Dr. Cramer's study      12 program for 40 years?      13 A. I'm aware who Dr. Welch is, and I've      14 certainly seen his name on papers. But now      15 his -- his role in these studies specifically, I      16 don't know if I can speak to other than he's      17 involved.      18 Q. He's testified that his only role was      19 in identifying the types of tumors involved in      20 the study to keep people honest.      21 Are you aware that Dr. Welch has repeatedly      22 refused to give -- refused to give a causation      23 opinion like you're giving today?      24 A. I'm not aware of Dr. Welch's opinions.      25 I didn't know that he was an expert, so I</p>	<p>1 A. I'm sorry. Where are you now?      2 Q. Same sentence. He just finishes it      3 with "Many subsequent studies found --      4 A. Okay.      5 Q. -- "talc use to increase the risk for      6 ovarian cancer."      7 But he just cites himself again from 1982;      8 correct?      9 A. Sorry?      10 Q. The only cite he provides for that      11 statement is his own study from 1982?      12 A. Oh, the one -- the No. 1?      13 Q. Mm-hmm.      14 A. Yes. That's his 1999, it says. 1999.      15 Q. Okay. Sorry about that. You're right.      16 And then he says, "However, the causality of      17 the relationship has been challenged for several      18 reasons."      19 Do you see that?      20 A. I do.      21 Q. And he says, "First, the association is      22 a relatively weak one; i.e., summary relative      23 risk of approximately 1.3."      24 Do you agree that a summary relative risk of      25 1.3 is a weak association?</p>
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<p>1 wouldn't have reviewed any of that testimony.      2 Q. Okay. You weren't provided with any of      3 his testimony or his reports in the litigation?      4 A. No. I was not aware that he was a      5 medical expert witness.      6 Q. Okay. Do you see under the      7 "Background" section here, it says, "Although      8 epidemiologic studies suggest talc may increase      9 ovarian cancer risk, there is no proof that talc      10 used externally reaches the pelvis"?      11 A. That's what it says.      12 Q. Are then if you look down in the -- I'm      13 sorry. I'm sorry.      14 If you look down in the first paragraph, he      15 mentions, "An epidemiologic association between      16 the use of cosmetic talc and genital hygiene and      17 ovarian cancer was first described in 1982."      18 That's Cramer citing Cramer; isn't it?      19 A. Let's see. Let me double-check. I'm      20 assuming because it's 1982. But let me      21 double-check. Or -- yeah. It's 1999. He's      22 referencing his 1999 paper.      23 Q. And he says, "And the many subsequent      24 studies found talc use to increase the risk for      25 ovarian cancer."</p>	<p>1 A. I've seen "weak" or "moderate" used to      2 describe a 1.3, but that doesn't mean it's not a      3 significant one, especially in a rare disease      4 like ovarian cancer.      5 MS. AHERN: Objection to the      6 nonresponsive portion.      7 Q. But I agree it's been described as      8 "weak," at least here by Dr. Cramer?      9 A. That's -- the sentence says, "First,      10 the association is a relatively weak one; i.e.,      11 summary relative risk of approximately 1.3."      12 Q. And he says, "Second, there's no clear      13 increase in risk with duration of use."      14 Do you agree with that, as of 2007, there      15 was no clear dose-response in the studies that      16 looked at talc and ovarian cancer?      17 A. I think there was evidence of a      18 dose-response by 2007.      19 Q. So do you disagree with Dr. Cramer's      20 statement in the 2007 publication that as of that      21 time, there was no clear increase in risk with      22 duration of use in most studies?      23 A. I wouldn't necessarily phrase it that      24 way: There's no clear increased risk. I think,      25 again, there isn't a lot of data, but what data</p>

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<p>1 there was -- I believe at that time, I'm trying      2 to think if I was in 2007 -- would be evidence      3 that there was a dose-response.</p> <p>4 Q. And which papers, prior to 2007, did      5 they find dose-response that was clear?</p> <p>6 A. I would have to look back.</p> <p>7 Okay. So I tried to do this in chronologic      8 order.</p> <p>9 Q. What page are you on?</p> <p>10 A. I'm looking at 16.</p> <p>11 Q. Page 16 of Exhibit 14?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. Were --</p> <p>14 A. I'm just trying to refresh my memory.</p> <p>15 So Harlow's -- let's see -- 1992 study was,      16 it looks like, the first one that I have listed      17 that had a dose-response -- evaluated for      18 dose-response.</p> <p>19 They both -- let's see. The confidence      20 intervals all included the null. Life- -- so      21 what I wrote here -- this is Page 18 -- "lifetime      22 application ORs when compared to control women      23 with no perineal talc exposure were 1.3, 4 less      24 than 1,000, with a confidence interval of 0.7 to      25 2.7; 1.5 for 1,000 to 10,000 with a confidence</p>	<p>1 2.4.      2 And for greater than 10,000, we're looking      3 at 1.0 to 3.0.</p> <p>4 Q. And when they just adjusted -- when      5 they excluded -- when they looked at lifetime      6 talc applications and ovarian cancer after      7 excluding use following hysterectomy or tubal      8 ligation, they found no evidence of an      9 exposure-response relationship, didn't they?</p> <p>10 A. Are you looking at the actual paper?</p> <p>11 Q. Do you need it?</p> <p>12 A. If you're asking me questions about it.</p> <p>13 Q. Yeah. That wasn't in your report -- or      14 is it?</p> <p>15 MR. ROTMAN: What is the "it" referring      16 to?</p> <p>17 Q. That particular finding is not in her      18 report on dose-response from Harlow in 1992?</p> <p>19 A. Well, yeah. Let me look at the --</p> <p>20 MS. AHERN: Sure.</p> <p>21 (Article entitled "Perineal      22 Exposure to Talc and Ovarian Cancer Risk"      23 marked Exhibit 20.)</p> <p>24 MS. AHERN: I'll mark as Exhibit 20 to      25 your deposition "Perineal Exposure to Talc and</p>
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<p>1 interval of 0.9 to 2.4; and 1.8 for greater than      2 10,000 with the confidence interval of 1.0 to      3 3.0.</p> <p>4 And then I also -- yeah. So that's after      5 2007, the Terry and the Lou studies.</p> <p>6 Q. You're looking at Harlow 1992?</p> <p>7 A. Yes. That's the paragraph I'm looking      8 at.</p> <p>9 Q. And Harlow 1992 found a      10 nonstatistically significant increased risk; is      11 that correct?</p> <p>12 A. So the confidence intervals included      13 the null. So, yeah, it was not statistically      14 significant. I'm not sure -- I don't have the      15 numbers here, though, of how many they had      16 dose-response data on, which would -- which might      17 increase the interval.</p> <p>18 In fact, if you look at the confidence      19 intervals, they're pretty wide, trending toward      20 higher.</p> <p>21 Q. What are the confidence intervals      22 you're looking at?</p> <p>23 A. For less than 1,000 lifetime      24 applications, we're looking at 0.7 to 2.7.      25 For 1,000 to 10,000, we're looking at 0.9 to</p>	<p>1 Ovarian Cancer Risk" by Harlow, 1992. That's my      2 only copy. Sorry.</p> <p>3 MR. ROTMAN: Exhibit 20.</p> <p>4 A. Okay. So, I'm sorry, where are you      5 looking?</p> <p>6 Q. Let me find it. Take your time, if you      7 need to. I'm trying to find my copy.</p> <p>8 Okay. If you look at Table 3, "Estimated      9 total lifetime perineal applications of talc      10 containing powders and cases and controls."</p> <p>11 A. Okay. I see Table 3.</p> <p>12 MR. ROTMAN: Is there a question?</p> <p>13 MS. AHERN: She asked to see the study.      14 I asked her to confirm that once they excluded      15 cases after hysterectomy or tubal ligation, there      16 was no exposure-response relationship.</p> <p>17 A. These look to be similar -- oh, I see.      18 Okay. Total applications.</p> <p>19 Well, if you actually look at the numbers,      20 the ones above, which are, I believe, what I      21 quoted in my report, so under "Total      22 applications."</p> <p>23 And then you're asking me about applications      24 excluding use after hysterectomy or tubal      25 ligation?</p>

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<p>1 BY MS. AHERN:</p> <p>2 Q. Mm-hmm.</p> <p>3 A. What was your question about it? I'm</p> <p>4 sorry.</p> <p>5 Q. There's no statistically significant</p> <p>6 dose-response relationship with lifetime</p> <p>7 application?</p> <p>8 A. So the confidence intervals are</p> <p>9 somewhat similar, but -- are somewhat similar, it</p> <p>10 looks like, to the top.</p> <p>11 Q. There's no statistically significant</p> <p>12 dose-response relationship, is there?</p> <p>13 A. They all include the null. That's</p> <p>14 correct. But, again, they're trending high.</p> <p>15 Q. But if they include the null, then it's</p> <p>16 consistent with the null hypothesis that there's</p> <p>17 no association; isn't that true?</p> <p>18 MR. ROTMAN: Objection.</p> <p>19 A. It's possible. The null hypothesis is</p> <p>20 included in "Possibilities."</p> <p>21 Q. It also basically means you can't</p> <p>22 exclude chance as a reason for the findings;</p> <p>23 correct?</p> <p>24 A. Again, it's possible. I would say it's</p> <p>25 trending higher, but it does include the null</p>	<p>1 dose-response?</p> <p>2 A. Well, I state in my report what the</p> <p>3 confidence intervals are. So certainly, I'm</p> <p>4 showing that it did include the null hypothesis.</p> <p>5 But I think it's still -- just because it's not</p> <p>6 statistically significant, I think it's still</p> <p>7 data, and I wouldn't completely discount it.</p> <p>8 But it does -- does contain the null. The</p> <p>9 numbers weren't super high, if I remember. But</p> <p>10 on their -- I'll have to find it.</p> <p>11 On -- in their abstract conclusion, they</p> <p>12 still say that "The greatest ovarian cancer risk</p> <p>13 associated with perineal talc use was observed in</p> <p>14 the subgroup of women estimated to have made more</p> <p>15 than 10,000 applications during years when they</p> <p>16 were ovulating and had an intact genital tract</p> <p>17 with the OR of 2.8 and a statistically</p> <p>18 significant confidence interval of 1.4 to 5.4.</p> <p>19 However, this exposure was found in only</p> <p>20 14 percent of the women with ovarian cancer."</p> <p>21 Q. Okay. But we were just asking -- you</p> <p>22 mentioned the study as support for a</p> <p>23 dose-response relationship in your report?</p> <p>24 A. As evidence of a dose -- a</p> <p>25 dose-response; again, with the caveat, which is</p>
<p style="text-align: center;">Page 263</p> <p>1 hypothesis.</p> <p>2 Q. Do you see on Page 25, in the first</p> <p>3 column on the left-hand side, the first full</p> <p>4 paragraph, "In our analysis"?</p> <p>5 Okay. The authors say, "In our analysis, we</p> <p>6 first calculated all genital applications of talc</p> <p>7 based on frequency and years of use. As a</p> <p>8 continuous variable in a multivariate model, no</p> <p>9 significant dose-response was observed between</p> <p>10 total genital applications of talc and ovarian</p> <p>11 cancer risk"; correct?</p> <p>12 A. That's what it says.</p> <p>13 Q. And the reason they excluded</p> <p>14 hysterectomy and tubal ligation is the next</p> <p>15 sentence, "because the translocation theory</p> <p>16 assumes an open genital tract, we then excluded</p> <p>17 application after tubal ligation or hysterectomy</p> <p>18 but observed no appreciable change in the</p> <p>19 dose-response."</p> <p>20 In other words, still no significant</p> <p>21 dose-response; correct?</p> <p>22 A. That's what it says.</p> <p>23 Q. So the authors interpreted both the</p> <p>24 data you cite in your report as well as the data</p> <p>25 you didn't cite in your report as showing no</p>	<p style="text-align: center;">Page 265</p> <p>1 here, that it includes the null hypothesis.</p> <p>2 Q. Okay. And what about Cramer in 1999?</p> <p>3 MR. ROTMAN: Objection. I don't think</p> <p>4 that's a question.</p> <p>5 MS. AHERN: Fair point.</p> <p>6 BY MS. AHERN:</p> <p>7 Q. In Cramer 1999, you've also cited as</p> <p>8 evidence after dose-response, correct, on Page 35</p> <p>9 of your report?</p> <p>10 A. I see that. Yes. It's listed in a</p> <p>11 reference list.</p> <p>12 Q. And the authors, including Cramer,</p> <p>13 basically say they "failed to demonstrate</p> <p>14 consistent dose-response relationships with</p> <p>15 measures of intensity of exposure."</p> <p>16 MR. ROTMAN: Do you have -- do you have</p> <p>17 the paper?</p> <p>18 MS. AHERN: Do you want the paper?</p> <p>19 MR. TISI: Is that the one you</p> <p>20 identified before?</p> <p>21 MS. AHERN: No. This is a new one.</p> <p>22 MR. ROTMAN: She's getting the paper</p> <p>23 out.</p> <p>24 MS. AHERN: I thought I had it too.</p> <p>25 Maybe it's in one of the boxes. Let me see if I</p>

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<p>1 can find my own copy. 2       Okay. Sorry. This is the only copy I 3 have right now. 4       THE WITNESS: Okay. 5       MS. AHERN: We can mark it, if you 6 want. 7 BY MS. AHERN: 8       Q. It's a copy of the Cramer 1999 9 publication that you cited in your report in 10 support of dose-response. 11      MR. TISI: Are you marking it? 12      THE COURT: I can if you want me to. I 13 just didn't want to mark my copy. 14      MR. KLATT: I don't think I do. 15      MS. AHERN: That's all right. I don't. 16 We'll mark Cramer -- oops, no, we won't because 17 this is the wrong study. Sorry. The old "wrong 18 study" trick. 19      THE WITNESS: I can't find that 20 information. Oh, I've got the wrong reference. 21 Sorry. All righty. 22      (Article entitled "Genital Talc 23 Exposure and Risk of Ovarian Cancer" marked 24 Exhibit 21.) 25</p>	<p>1 in the table. Let me see. 2       Q. I think so. If you want to go to -- 3       A. Oh. 4       Q. You got it. 5       A. Yes. I see it now. Sorry. It was 6 buried in Table 3, very small print. Okay. Yes. 7       So Table 3, years of use. Yup. 8       Q. Do you see they're not showing a 9 statistically significant dose-response 10 relationship? 11      A. So for less than 20 years, the 12 confidence intervals were 1.16 to 3; at 20 and 30 13 and greater than 30, they did -- the confidence 14 intervals did include the null. 15      But, again, I don't know how many -- I can't 16 remember. Oh, here are the cases. 17      Yeah. So there are 55, less than 20 cases; 18 thirty-two 20 to 30; and 59 greater than 30. 19      Q. And you see also the frequency 20 analysis? It also did not find a significant 21 dose-response relationship as a statistically 22 significant dose-response relationship? 23      A. Yes. For less than 30 years, the 24 adjusted OR was 2.21 with a confidence interval 25 of 1.37 to 3.56.</p>
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<p>1 BY MS. AHERN: 2       Q. Okay. So, Doctor, this is Exhibit 21, 3 which is "Genital Talc Exposure and Risk of 4 Ovarian Cancer," Dan Cramer, 1999. 5       A. Okay. 6       Q. This is something else. 7       Can you find -- I don't have it in front of 8 me, so I'm going to rely on you to find the 9 tables that show their dose-response analysis. 10      MR. ROTMAN: You made that Exhibit 21? 11      MS. AHERN: Yes. 12      MR. TISI: It's 21. Yes. 13      THE WITNESS: Would that be Table 2, 14 what you're referring to (indicating)? 15 BY MS. AHERN: 16      Q. I believe the numbers were -- they were 17 looked at in terms of zero years' duration, less 18 than 20, 20 to 30, and greater than 30. 19      Do you see that on there? 20      A. I'm looking. This one says "less 21 than -- frequency of use." 22      Q. There's a frequency and a duration. 23      A. Okay. 24      Q. Yeah. 25      A. Sorry. Why am I not seeing it? It's</p>	<p>1 The 30 to 39 was adjusted OR of 1.17 with 2 confidence intervals .78 to 1.76. 3       And the 40-plus adjusted OR was 1.57 with 4 confidence intervals of 0.8 to 3.10. 5       Q. So not only did the point estimate go 6 down with more use, but the higher the 7 concentration, there was also no statistical 8 significance; correct? 9       A. Yeah. I mean, the numbers -- so the 10 only one that doesn't include the null -- let me 11 just double-check. 12      Actually, there are two. So the less than 13 20 years or less than 30 per month are 14 statistically significant. 15      Q. It's only the first dose category in 16 each group -- 17      A. Yeah. 18      Q. -- shows statistical significance. 19      And as the doses got higher, the exposure 20 frequency got higher, the point estimates went 21 down and statistical significance went away; 22 correct? 23      A. The confidence intervals did include 24 the null. And I think this illustrates how 25 difficult sort of dose and frequency can be to</p>

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<p>1 study because we don't really know what the doses      2 are, and we don't really have granularity as far      3 as frequency of use. Well, I have to look at --      4 Q. These are studies that you cited in      5 your report as evidence of a dose-response,      6 correct, the Harlow and the Cramer papers? You      7 both cited yourself.      8 Did you evaluate the internal validity of      9 those studies and critically evaluate the methods      10 and study populations when you included them in      11 your report?      12 A. Let me -- well, I said -- this is the      13 sentence -- "Most have found an increased risk of      14 ovarian cancer with increased exposure." So,      15 yet, when studies have evaluated duration of      16 frequency of perineal talc use.      17 So this list is the studies that evaluated      18 duration and frequency of perineal talc use. And      19 I said, "Most have found an increased risk." So      20 what I'm citing here are the studies that looked      21 at duration and frequency.      22 Q. Okay. And we were referring to      23 Cramer's 2007 publication where he himself says      24 that the association has been challenged because      25 it's weak and because there's no clear increase</p>	<p>1 "application of talc."      2 "Another factor that may affect the      3 dose-response relationship is whether use      4 occurred at a time when the female tract was      5 open. There is evidence from several studies      6 that the talc/ovarian cancer association is      7 modified by closure of the female tract as a      8 result of tubal ligation or hysterectomy.      9 Q. Doctor, did they say they didn't find a      10 dose-response relationship?      11 A. I'm trying to find what they said other      12 than that on Page 355.      13 Yeah. They said, "Studies that have      14 dose-response, including this one, have failed to      15 demonstrate consistent dose-response      16 relationships."      17 But it goes on to qualify with the      18 difficulty of measuring dose and frequency, which      19 is what I described earlier.      20 Q. Mm-hmm.      21 (Article entitled "Perineal Talc      22 Exposure and Epithelial Ovarian Cancer Risk      23 in the Central Valley of California" marked      24 Exhibit 22.)</p>
<p>1 in risk with duration of use.      2 And you didn't agree with that statement,      3 and you referred me to Harlow 1992; correct?      4 A. I was going to where I mentioned the      5 dose-response studies.      6 Q. Okay. Just to button up and finish up      7 with Cramer 1999, if you look at Page 355, the      8 authors included, "They failed to demonstrate      9 consistent dose-response relationships with      10 measures of intensity of exposure."      11 Do you see that?      12 A. I'm sorry. Where are you?      13 Q. On Page 355.      14 A. Okay. I'm seeing "in attempting" --      15 sorry. I see, "Most talc and ovarian cancer      16 studies that have addressed dose-response,      17 including this one, have failed to demonstrate      18 consistent dose-response relationships with      19 measures of the intensity of the exposure,      20 especially when the trend is examined among users      21 only. In attempting to address this weakness, we      22 point out that it is difficult to quantify the      23 amount of powder actually used and degree of      24 perineal dusting that might constitute an      25 application of talc," quote/unquote around</p>	<p>1 BY MS. AHERN:      2 Q. Okay. The next one -- are you done,      3 sorry, with that one?      4 A. If we're moving on, sure.      5 Q. If you're done.      6 The next one you mention, you cite in your      7 report for dose-response is Mills 2004, which I'm      8 handing you now marked as Exhibit 22.      9 Oh, yeah. We'll leave that here for right      10 now.      11 A. Okay.      12 MR. ROTMAN: Can I see the one you just      13 finished with?      14 MR. TISI: This is 22; right?      15 MS. AHERN: Yes, sir.      16 BY MS. AHERN:      17 Q. And this one, you're welcome to read      18 through it if you want. All I wanted to point      19 out is if you look right up front in the      20 abstract, a little more than midway down, they      21 say, "The odds ratio for ever use of talc was      22 1.37 with the confidence interval of 1.02 to 1.85      23 compared to never users. However, no      24 dose-response association was found."      25 Do you see that?</p>

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<p>1 A. I see where it says that. 2 Q. And if you want to look through there 3 and convince yourself of that, go for it. I 4 think the table that we're looking at is Table 2 5 on Page 460. 6 A. Yeah. The 4 to 12 years had an OR of 7 1.86 that was statistically significant at 1.16 8 to 2.98. But the others, which were never -- 9 which, of course, is the null, 4 to 12 years, 10 which -- oh, the 13 to 30 was adjusted OR of 11 1.45, confidence interval .9 to 2.32. 12 And then the greater than 30 years was OR of 13 1.22 with confidence interval of .72 and 2.08. 14 So the 13 to 30 and the greater than 30 includes 15 the null. 16 And then if we look at frequency, cumulative 17 use, frequency types duration, there was a 18 statistically significant increase with second 19 quartile and third quartile divisions. But then 20 it dropped in the fourth quartile, the highest 21 exposure. 22 And, you know, again, sort of difficulty in 23 measuring this. But you do see an increase in 24 the second and third quartile, between the second 25 and third, that was statistically significant.</p>	<p>1 Q. I was trying to point you a little bit 2 toward this. It's Page 463. There's some 3 discussion of it. 4 If you look at the third paragraph down, "As 5 in other studies, the present study did not find 6 a clear dose-response based on duration of use or 7 cumulative use." 8 And then it says, "Limiting the analysis of 9 dose-response to women who reported ever use of 10 talc did not affect the results, data not shown. 11 The lack of dose-response between talc use and 12 epithelial ovarian cancer may be explained by the 13 inability to quantify the actual amount of talc 14 used per application and the timing of the 15 application." 16 A. Yeah. So with that caveat. 17 Q. Well, the findings are what they are; 18 right? 19 The findings are no dose-response 20 relationship? 21 A. The findings are what they are. But, 22 again, it's not an easy -- there's not huge 23 numbers in these cases. 24 And, again, you still don't know from woman 25 to woman what one dose is, so there's a ton of</p>
<p style="text-align: center;">Page 275</p> <p>1 And then -- 2 Q. But the authors themselves interpret 3 their data as no dose-response association; 4 correct? 5 A. In the abstract, that's what they 6 state. I'm trying to figure out what their -- 7 what they said. They must have said a little bit 8 more. 9 Q. Doctor, you reviewed this study before; 10 right? 11 A. I did. Yes. 12 Q. Okay. 13 A. I'm just refreshing my memory. 14 Q. Okay. If you look at Page 463. 15 MR. ROTMAN: Are you changing the 16 topic? 17 MS. AHERN: No. Same topic. 18 MR. ROTMAN: She was looking for 19 something as part of a prior answer. 20 BY MS. AHERN: 21 Q. As part of your prior answer that there 22 was no dose-response? 23 A. As part of the answer that they stated 24 that in the abstract. I was trying to find out 25 where they had a discussion.</p>	<p style="text-align: center;">Page 277</p> <p>1 variability. It's not like a cigarette, where, 2 you know, from one cigarette to the next or, you 3 know, a drug dose is probably a more accurate 4 analogy, you know. 5 Q. True. But just because it's difficult 6 to study, it doesn't mean if we could study it 7 better, we would get a positive result, does it? 8 A. I -- oh, my thing is not working. I 9 think I have to plug my thing in. 10 MR. ROTMAN: Can you? 11 COURT REPORTER: I'd have to break to 12 do it. 13 MR. ROTMAN: Let's go off the record. 14 THE VIDEOGRAPHER: Off the record. 15 4:37 p.m. 16 (A recess was taken.) 17 THE VIDEOGRAPHER: Back on the record, 18 4:44 p.m. 19 BY MS. AHERN: 20 Q. Okay. Doctor, you saw the Mills paper 21 in front of you? 22 A. Yes. 23 Q. Okay. Could you look at your report on 24 Page 21? 25 (Witness complies.)</p>

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<p>1 A. Okay. 2 Q. Let's see, where is my copy? 3 And turn to Page 3 of the Mills publication. 4 A. Page 3, which would be Page 460? 5 Q. That's a good question. 6 Where is my Mills publication? 7 MS. AHERN: Do you have it? 8 MR. TISI: Sure. 9 MS. AHERN: Thank you. 10 Oh, I know where it is. 11 BY MS. AHERN: 12 Q. I'm sorry. I thought I had the 13 specific passage marked. And I do, somewhere in 14 here. Okay. Sorry. It's on Page 460. I 15 apologize. 16 A. Okay. 17 Q. All right. Do you see on the Mills 18 publication on Page 460 that bottom paragraph on 19 the left, "ever use of talcum powder"? 20 A. Yes. 21 Q. And if you read down toward the bottom 22 part of that paragraph, on the fourth line from 23 the bottom, the sentence starts "Duration of 24 use." 25 A. Okay.</p>	<p>1 Q. Is there a reason that that entire 2 portion of your report is copied identically from 3 Mills except for the qualifier that the pattern 4 was not clear-cut for dose-response? 5 A. Well, I think it still has the same 6 meaning. 7 Q. Without the qualifier? 8 A. I think the qualifier is in the -- in 9 the data. 10 Q. Okay. 11 A. I don't think I was -- I wasn't trying 12 to make it sound anything different than what it 13 was. I think I was trying to report the data. 14 Q. Okay. All right. And, Doctor, if you 15 turn to Page 10 of your report, the section on 16 inflammation. 17 Are you there? 18 A. Yes. 19 Q. You start on the second paragraph under 20 "Inflammation" discussing oxidative stress. 21 A. Okay. 22 Q. Okay. Were you aware that a 23 significant amount of the section of your report 24 on oxidative stress is copied verbatim? More 25 than 60 percent of it, I think, is copied</p>
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<p>1 Q. "Duration of use of talcum powder was 2 associated with increased risk, although the 3 pattern was also not clear-cut in that the point 4 estimate peaked among those reporting 4 to 12 5 years of use and declined somewhat among those 6 reporting longer duration of use." 7 Do you see that statement? 8 A. I see that. Yup. 9 Q. And if you look at your report on 10 Page 21, the top paragraph, about midway, a 11 little -- well, a third of the way down, you pick 12 up with "Duration of use of talc was also 13 associated with increased risk, although the risk 14 peaked." 15 Do you see that statement? 16 A. Yes. 17 Q. If you compare those statements, are 18 they almost identical with the exception of the 19 statement by Mills that the pattern was not 20 clear-cut? 21 A. They are similar. This might have 22 been, like I described earlier, where, if I was 23 taking notes, some of the language might have 24 gotten incorporated, although I do have the 25 citation.</p>	<p>1 verbatim from Dr. Saed's 2018 publication? 2 A. Again, if the language is similar, it 3 was not an intentional. I am citing him here, so 4 it's -- you know, it's clear that those are the 5 references. Again, it might have been due to 6 note-taking, but the citation is clear. 7 Q. Do you ever take verbatim language out 8 of another scientist's work and not set it off in 9 quotation marks in your professional work? 10 A. I think I've cited the source here. 11 It's -- so it's not -- again, it's not like I was 12 intentionally copying his words. It was, again, 13 probably an editing while I was taking notes, but 14 the citations are clear. 15 Q. Is your -- is the underlying 16 understanding that you have related to oxidative 17 stress and inflammation drawn primarily from 18 Dr. Saed's work? 19 A. No. I mean, oxidative stress and 20 inflammation is something that we study -- that 21 I've studied. 22 Q. Have you ever published a study on 23 oxidative stress or redox biology? 24 A. I have not published on oxidative 25 stress.</p>

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<p>1 Q. What sort of work as a pathologist have 2 you done that incorporates redox biology? 3 A. Well, again, this is part of our 4 medical training. Certainly in training to be a 5 physician, that is something that we learn. And, 6 you know, pathologists do quite frequently come 7 across inflammatory -- inflammation literature. 8 Q. Are you -- is it your position that the 9 information in your report under "Inflammation" 10 that discusses oxidative stress and redox biology 11 is common knowledge among pathologists? 12 A. That oxidative stress and inflammation, 13 yes. I think -- yes. I think that's widely 14 accepted. 15 Q. The specific information contained on 16 Pages 10 and 11 of your report that was drawn 17 from Dr. Saed's work, is that information that is 18 common knowledge? 19 The specific enzymes that are discussed, the 20 research on these issues, is that specific 21 information there common knowledge? 22 A. It's common knowledge that these types 23 of cancer are associated with inflammation, and 24 certainly oxidative stress is part of 25 inflammation.</p>	<p>1 A. I did attribute -- I certainly cited 2 him in several places in this area. And, again, 3 it was not an intentional copying. Again, it 4 might have just happened with my editing, but I 5 certainly tried to cite everything that I was 6 looking at in the proper place. 7 But I do believe that it's common knowledge 8 that chronic inflammation can cause different 9 types of cancer. This is not really new data. 10 Q. Dr. Saed says that it's new data. 11 A. In what respect, though? If we're 12 talking about myeloperoxidase, yes. But I'm 13 talking about oxidative stress and chronic 14 inflammation with known association with certain 15 types of cancer. 16 Q. So it's your testimony that the 17 verbatim text that you used in the section from 18 Dr. Saed's 2018 paper was appropriately cited and 19 attributed to him? 20 MR. ROTMAN: Objection. 21 A. Again, I'm not sure it's absolutely 22 verbatim, but I certainly cited him in every 23 place that I was referencing. 24 Q. Okay. We'll just move on. 25 (Highlighted copy of Dr. Kane's</p>
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<p>1 Q. Was this common knowledge to you before 2 you reviewed Dr. Saed's 2018 publication? 3 A. Yes. I was just citing his report at 4 this point. 5 Q. Are you aware you also cited his 6 underlying citations in the same spots that he 7 cited them? 8 A. That's possible because I reviewed his 9 citations as I was reading his citations. 10 Q. Did Dr. Saed give you permission to 11 copy his -- the language from his publication? 12 A. I wouldn't characterize it as 13 "copying." I think it may be similar language, 14 again, because I was writing as I was reading. 15 But I am certainly clearly citing his work and 16 the other citations. 17 Q. Do you agree that Dr. Saed's 2018 18 paper is a compilation of his own synthesis and 19 review of the underlying articles that he 20 incorporated into his paper, and do you think 21 it's appropriate for you to just lift the 22 language from his paper and the citations that he 23 found and synthesized and put it in your report 24 and not attribute it to him with quotation marks? 25 MR. ROTMAN: Objection.</p>	<p>1 expert report marked Exhibit 23.) 2 BY MS. AHERN: 3 Q. Doctor, I've marked as Exhibit 23 to 4 your deposition a highlighted copy of your report 5 that shows the verbatim text that has been 6 carried over from various publications into your 7 report. 8 If you turn to Page 10 and 11, you'll see 9 that the highlighted portions are copied directly 10 from Dr. Saed's work. 11 MR. ROTMAN: Do you have a copy for me 12 of this exhibit? 13 MS. AHERN: Oh. I do. Sorry about 14 that. 15 MR. ROTMAN: So we're at Page 10 and 16 11? 17 MS. AHERN: That's just for the Saed 18 publication. And there's one in there that Saed 19 was also on. 20 MR. ROTMAN: Does she have the Saed 21 publication in front of her? 22 MS. AHERN: I can find it for you. 23 BY MS. AHERN: 24 Q. But my point is, are you aware that 25 that -- that there's a significant portion of</p>

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<p>1 that section of your report that is just 2 cut-and-pasted from Dr. Saed's work? 3       A. I don't believe -- again, it's -- it 4 wasn't intentional with the citations, and it 5 could have happened with my note-taking or other 6 suggested input. But, again, I cited -- I 7 certainly cited him in that section. 8       Q. Okay. 9       MR. TISI: Did you mark that? 10      MS. AHERN: Hmm? 11      MR. TISI: Did you mark that as an 12 exhibit? 13      MS. AHERN: Yes. I think it's 23. 14 Sorry. 15      MR. TISI: That's okay. 16      MR. ROTMAN: Do you have the Saed in 17 front of you? 18 BY MS. AHERN: 19      Q. I think it's -- it wasn't intentional 20 is your testimony, and it's probably just a 21 result of your note-taking process; is that 22 correct? 23      A. Well, because I cited him specifically, 24 certainly it wasn't intentional to be verbatim. 25 And I'm not sure exactly the process, but</p>	<p>1 biology and inflammation, are you? 2       A. I am not currently participating in a 3 study of oxidative stress or redox biology. 4       Q. You don't have any funding related to 5 oxidative stress and inflammation, do you? 6       A. No, I do not. 7       Q. Have you ever applied for any funding 8 in that area? 9       A. No. I have not. 10      Q. Have you ever authored a systematic 11 review of the literature on oxidative stress and 12 inflammation? 13      A. Oxidative stress and inflammation, no. 14 I don't believe I have. 15      Q. Have you ever authored a systematic 16 review of the literature on oxidative stress and 17 cancer? 18      A. No. I have not authored a systematic 19 review on that. 20      Q. Okay. Doctor, moving on to 21 inflammation and ovarian cancer. 22      Generally, on inflammation, can you cite to 23 a published experiment that was conducted in 24 animals in vivo that establishes a role of any 25 particular inflammatory cell or cytokine or</p>
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<p>1 certainly I'm citing him several times there. 2       Q. Okay. That's fine. We'll just move 3 on. 4       And, Doctor, just to be clear, I understand 5 your testimony is that it is common knowledge to 6 pathologists that oxidative stress and 7 inflammation are related; correct? 8       A. Yes. 9       Q. Okay. But you are -- we're talking 10 about oxidative stress and redox biology 11 specifically as a field of study or research. 12      You're not an expert in that field of study 13 or research, are you? 14      A. I certainly have read literature in 15 that area. 16      Q. Does that make you an expert? 17      A. I'm -- I mean, I'm familiar with 18 literature in the area. That's -- that's my 19 answer. 20      Q. Okay. But you don't conduct studies in 21 oxidative stress and redox biology, do you? 22      A. I do not conduct studies in oxidative 23 stress and redox biology. 24      Q. You're not currently participating in a 25 study looking at oxidative stress or redox</p>	<p>1 enzyme in tumor regenesis? 2       A. Oh. Let me -- let me bring up my 3 inflammation section. Sorry. I'm just 4 refreshing myself as to what I stated in my 5 report. 6       Oh, this is low battery again. I don't 7 think this is plugged in. 8       MR. ROTMAN: Can we take five minutes 9 off the record? 10      MS. AHERN: Yes. 11      THE VIDEOGRAPHER: Off the record, 12 5:02 p.m. 13      (A recess was taken.) 14      THE VIDEOGRAPHER: Here begins Media 15 No. 6 in today's deposition of Sarah Kane, M.D. 16 Back on the record, 5:28 p.m. 17      (Article entitled "Talcum 18 powder, chronic pelvic inflammation and 19 NSAIDs in relation to risk of epithelial 20 ovarian cancer" marked Exhibit 24.) 21 BY MS. AHERN: 22      Q. Dr. Kane, I'm marking what's been -- 23 well, I'm marking Exhibit 24 to your deposition, 24 which is a copy of the Merritt 2008 publication. 25 And I'm sorry, I don't have an extra. I'm going</p>

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<p>1 to share. 2 It's "Talcum powder, chronic pelvic 3 inflammatory -- sorry, chronic pelvic 4 inflammation and NSAIDs in relation to risk of 5 epithelial ovarian cancer." 6 And you cite Dr. Merritt's paper a couple of 7 times in your report; is that correct? 8 A. I believe I cited it, yes. 9 Q. I think you cite it as a statistically 10 significant positive talc study on Page 17 of 11 your report? 12 A. Oh, let me get to that, if that's the 13 section I'm thinking of. 14 Q. There are a couple of places? 15 A. There was -- yes. This happened in 16 editing. I believe if this is -- so the sentence 17 ended up, it originally didn't have the 18 "statistically significant." It was just, you 19 know, an odds ratio greater than one and listed. 20 And then I mistakenly didn't delete. When I 21 changed it to "statistically significant," for 22 some reason -- I don't know if it happened in the 23 editing between additions or something -- somehow 24 I seem to remember deleting them. But in the 25 final, they ended up all there. So that was a --</p>	<p>1 of multiple publications. 2 A. Right. 3 Q. You're saying that some of those 4 publications shouldn't be in there because you 5 added "statistically significant" as a criteria 6 later? 7 A. Exactly. 8 Q. Okay. That's actually not my question 9 about Merritt, but thank you. 10 A. I knew that was going to come up -- 11 Q. That's okay. 12 A. -- at some point. 13 Q. While we're there, since we're sitting 14 here looking at this, so these are -- you listed 15 out case-control studies addressing talc, and 16 they're supposed to be those that have 17 statistically significant odds ratios; correct? 18 A. That's correct. That was the 19 intention. 20 Q. And Gertig 2000 is there, and Houghton 21 2014 are there, and they're obviously cohort 22 studies? 23 A. So, again, I think that somehow that 24 paragraph got all -- and I didn't catch it in the 25 final edits.</p>
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<p>1 MR. ROTMAN: What page was this? 2 A. -- typographical error. 3 It's in there twice. I noticed it after I 4 submitted it, and it was one of those -- 5 Q. Are you saying Merritt is not 6 statistically significant? 7 A. So I know which -- again, I'd have -- I 8 have to go through. It's been a long day, and 9 the names are starting to get all confused. 10 Q. Yeah. 11 A. But I know that that sentence, with 12 "all of those" at the end of that sentence, is 13 incorrect because I had changed -- I had meant to 14 list cumulatively the statistically significant 15 ones and ended up -- 16 Q. Okay. So just to clarify for the 17 record, on Page 17, we're talking about the first 18 full paragraph that says, "In addition to the 19 Cramer 1982 study, numerous other case-control 20 studies addressing talc use and ovarian cancer 21 have shown statistically significant odds ratios 22 greater than one indicating talc use is 23 associated with an increased ovarian cancer 24 risk." 25 And then there's a string cite with a number</p>	<p>1 Q. Okay. 2 A. I know that that was at least a 3 different paragraph at first, possibly two 4 paragraphs that got condensed. And then somehow, 5 the references didn't get changed in the final. 6 Q. Okay. Do you happen to know -- and if 7 you don't it's okay -- but do you happen to know 8 which of these studies should be there and which 9 should be removed? 10 A. Off -- I would want to look just to 11 make sure. 12 Q. Okay. 13 A. But I'm -- if I am -- I'd want to look 14 just to make sure, but I know there are some that 15 should not be there. 16 Q. All right. But looking at Merritt, 17 there are a couple of places where Merritt is 18 cited in your report. One is Page 17 in that 19 paragraph we just looked at. Another is Page 28 20 in Section -- the "Pooled study regarding talc 21 use and ovarian cancer" section. 22 It says some -- let's see, you're talking 23 about the advantages of pooled studies, and you 24 cited Merritt 2008. 25 A. Okay.</p>

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<p>1 Q. And then on Page 35, Merritt is cited. 2 "Studies evaluating duration and frequency of 3 perineal use, most have found an increased risk 4 of ovarian cancer with increased exposure." 5 We already went through this paragraph 6 earlier -- 7 A. Yeah. Yeah. 8 Q. -- and discussed Merritt a little bit 9 in that context. 10 MR. ROTMAN: Page 30 -- the last one 11 was Page 35? 12 MS. AHERN: Thirty-five. Yeah. I 13 apologize. We may not have discussed Merritt. 14 BY MS. AHERN: 15 Q. But looking at Merritt now, you're 16 aware that Merritt looked specifically at 17 inflammatory conditions as part of their 18 exploration of the hypothesis that chronic 19 inflammation could lead to ovarian cancer; is 20 that right? 21 A. Yes. There was a component from what I 22 remember. 23 Q. They say in the abstract that "Chronic 24 inflammation has been proposed as the possible 25 causal mechanism that explains the observed</p>	<p>1 endometriosis. 2 And do you see if you turn to -- I'm trying 3 to get through this quickly. You're welcome to 4 point out anything you want, but I kind of want 5 to move us along. 6 A. Okay. 7 Q. If you look at the "Discussion" 8 section, I, unless I missed it, on Page 174, the 9 right-hand column, second full paragraph, they 10 note that "It has been hypothesized that talc is 11 linked to ovarian cancer development through 12 inflammation. However, evidence linking an 13 inflammatory response with talc contamination of 14 the ovaries is lacking." 15 Do you agree or disagree with that statement 16 that evidence linking an inflammatory response 17 with talc contamination of the ovaries is 18 lacking? 19 A. I don't know if I would phrase it that 20 way. Have there been studies that have followed 21 talc from application up to the ovaries and 22 documenting an inflammatory response after talc? 23 No. There's not going to be that study. 24 That would be -- I don't think you could do 25 that study today with talc being called by the</p>
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<p>1 association between certain risk factors such as 2 the use of talcum powder or talc in the pelvic 3 region and epithelial ovarian cancer." 4 Do you see that? It's in the abstract, the 5 first sentence? 6 A. Yeah. Okay. The first sentence. 7 Q. Okay. They go on to say, "To address 8 the issue, we evaluated the potential role of 9 chronic local ovarian inflammation in the 10 development of the major subtypes of epithelial 11 ovarian cancer." 12 Do you see that? 13 A. Yes. 14 Q. Okay. And just want to ask you: They 15 conducted the study as a case-control study 16 looking at 2319 women with epithelial ovarian 17 cancer; correct? 18 A. I don't remember the exact number, but 19 I will -- I will -- 20 Q. I think that's -- that's okay. 21 A. I don't remember the exact number. 22 Q. Okay. So they looked at a number of 23 factors that are theoretically associated with 24 chronic inflammation, didn't they, including 25 pelvic inflammatory disease and talc use,</p>	<p>1 IARC a possible carcinogen. I don't think you 2 could design that study right now and do that in 3 women. 4 But, again, I think -- I think it's still a 5 highly compelling, plausible mechanism because we 6 know talc can cause inflammation, and 7 inflammation is associated with certain cancers, 8 including certain types of ovarian cancers. 9 So I don't know if I would state it that 10 way. 11 Q. When you say inflammation is associated 12 with ovarian cancer, what studies are you 13 referring to? 14 A. I'm referring to, for example, clear 15 cell carcinomas that have arisen from 16 endometriotic lesions that we've talked about 17 before. 18 Q. And those cells are -- the originating 19 cells are thought to come from the endometrium 20 itself, the uterus; correct? 21 A. I don't know if we know for sure. I 22 mean, is it endometriosis that's in the ovary 23 causing chronic inflammation in the ovarian cells 24 that are causing the clear cell? I don't know if 25 that's been completely delineated.</p>

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<p>1       Q. But there are markers that will 2 distinguish ovarian surface epithelial cells from 3 endometrioid cells which resemble endometrial 4 cells; correct?</p> <p>5       A. There are some stains that you can do. 6 But, again, I don't know if it's going to be -- 7 been completely elucidated.</p> <p>8       Q. Are you aware of recent studies that 9 have demonstrated that there is some abnormality 10 in the endometrium of women who develop 11 endometriosis when compared to women who don't 12 develop endometriosis?</p> <p>13      A. I'm aware that retrograde migration of 14 the endometrium is thought to -- has been 15 associated with endometriosis. I don't know what 16 you mean by "abnormalities" of the -- you have to 17 be more specific. I can't --</p> <p>18      Q. I don't have the publication with me. 19 I was just asking if you were aware of those 20 studies.</p> <p>21      A. I probably read them at some point, but 22 off the top of my head, I'm not really sure 23 without knowing more specifically.</p> <p>24      Q. And would you agree that the studies, 25 though, that show a decreased risk of ovarian</p>	<p>1       inflammatory mechanism in the development of 2 epithelial ovarian cancer. However, experimental 3 evidence that perineal talc use elicits an 4 inflammatory response in the ovaries is lacking, 5 and overall, we conclude that chronic 6 inflammation does not play a major role in 7 development of ovarian cancer."</p> <p>8       Is there a reason you didn't cite the 9 Merritt study in your report specifically when 10 discussing evidence of chronic inflammation and 11 ovarian cancer, a link between those two?</p> <p>12      A. In the places that I -- let me just 13 double-check. Places that I mention, was I 14 not -- I wasn't talking about inflammation. Is 15 that what you're --</p> <p>16      Q. Yes. You agree you cited Merritt in 17 several places in your report?</p> <p>18      A. Yes.</p> <p>19      Q. But you didn't cite anything about the 20 inflammation findings from Merritt.</p> <p>21      A. I'm not sure I can completely agree 22 with their conclusion. It's true we don't 23 have -- like I mentioned before, we don't have a 24 study that has looked at women who use talc, 25 follow it up, and then see chronic inflammation</p>
<p style="text-align: center;">Page 299</p> <p>1       cancer for women who have tubal ligation are 2 studies -- well, are more highly associated with 3 endometrioid clear cell carcinomas than with 4 high-grade serous?</p> <p>5       A. With tubal ligation, off the top of my 6 head, I believe that's -- that that's the case.</p> <p>7       But with salpingectomy, which removes the 8 fallopian tube fimbriae, there's -- that 9 decreases the risk of serous carcinomas.</p> <p>10      Q. To a lesser extent, then, the decrease 11 for clear cell and endometrioid, which some 12 people have suggested supports the retrograde 13 migration of endometrial cells into the abdominal 14 cavity?</p> <p>15      A. Some people have said that that 16 supports the retrograde migration of the 17 endometrial cells. That is correct.</p> <p>18      Q. And I got off topic. We're looking at 19 Merritt. Page 174, if you look, let's see -- 20 here it is. Sorry. I apologize, on Page 175.</p> <p>21      The very bottom of the summary paragraph, it 22 says, "The elevation in ovarian cancer risk 23 associated with use of talc in the perineal 24 region that we and others have observed has been 25 regarded as the main evidence supporting an</p>	<p style="text-align: center;">Page 301</p> <p>1       in the ovary.</p> <p>2       But I think that's going to be -- again, we 3 don't know how long that chronic inflammation is 4 going to be there. We don't know what dose is 5 getting into the ovary.</p> <p>6       I still think -- and, again, this is the 7 plausibility part of it -- I think there's still 8 compelling evidence that talc can cause an 9 inflammatory response that would explain the risk 10 of increased risk of ovarian cancer with talcum 11 powder products.</p> <p>12      So, I mean, I certainly read this. It had 13 some good information in it. I don't think I was 14 purposely trying to leave out something that had 15 evidence. This was their opinion.</p> <p>16      And I'm -- I don't know if I would phrase it 17 that way, the exact words that they use.</p> <p>18      Q. Well, if those are exactly their 19 findings here -- if you look at the top of the 20 summary paragraph, "In summary, most factors that 21 could potentially cause ovarian inflammation such 22 as pelvic inflammatory disease, HPV infection, 23 and postpubertal mumps were not associated with a 24 significant elevation in ovarian cancer risk in 25 our study. In addition, the expected corollary,</p>

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<p>1 an inverse association with regular use of      2 anti-inflammatory medications, was also not      3 observed -- or was not observed."</p> <p>4 A. Yes. Yeah. Yeah.</p> <p>5 Q. They looked at multiple sources or      6 multiple causes of inflammation in the pelvic      7 region and did not find an association with the      8 risk of ovarian cancer, and they didn't find a      9 decreased risk in people that used      10 inflammatory -- anti-inflammatory medications.</p> <p>11 A. I think I mentioned --</p> <p>12 Q. So this is an inflammation study, isn't      13 it?</p> <p>14 A. Yeah. I think I mentioned in -- about      15 NSAIDs that I might have cited them in that      16 section, that the evidence was not consistent      17 with NSAIDs, if I remember correctly.</p> <p>18 I definitely looked at this paper when I was      19 looking at NSAID and aspirin use and certainly      20 inflammation as well. So...</p> <p>21 Q. It's actually not cited anywhere with      22 NSAID use or regarding inflammation at all.      23 So maybe it was an earlier draft and was      24 removed at some point?</p> <p>25 A. It's possible.</p>	<p>1 Q. I'm sorry. I'm just referring      2 generally.</p> <p>3 Do your opinions, in part, depend on the      4 finding of talc in ovaries?</p> <p>5 A. No. Because I think, again, it's      6 difficult to find talc in the ovaries. So I      7 would not expect to see -- to find, to      8 histologically find talc in every ovary of a      9 woman who has used talcum powder products. I      10 think that would be extremely difficult to do in      11 every patient.</p> <p>12 And I know we talked about the MUC-1 theory      13 earlier, but if that is the mechanism, that would      14 not require talc to get to the ovary.</p> <p>15 So, no, I don't think it's necessary to find      16 talc in the ovary in every woman to come --      17 that's a user.</p> <p>18 Q. Let's talk about evidence for      19 talc-induced inflammation in the ovary.</p> <p>20 For instance, you've cited the Heller study      21 from 1996 in your "Migration translocation,      22 inhalation, and lymphatic transport" section on      23 Page 14.</p> <p>24 A. Mm-hmm.</p> <p>25 Q. Heller actually states in their study</p>
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<p>1 Q. And you also -- you cite -- you do cite      2 some of the NSAID studies and aspirin studies,      3 but you leave out others. You leave out Baandrup      4 2013, which was a negative study; Bonovas, 2005,      5 which was a negative study; Ni, 2012, which was a      6 negative study.</p> <p>7 When you did your review of inflammation      8 including anti-inflammatory medications and the      9 risk of ovarian cancer, did you pull out more      10 studies in review than you actually included in      11 your report?</p> <p>12 A. Yes. There are definitely more studies      13 than were cited in my report.</p> <p>14 Q. Is there a reason you didn't cite the      15 negative studies?</p> <p>16 A. I didn't intentionally leave out the      17 negative studies, but I do mention that the      18 evidence had been inconsistent with NSAID.</p> <p>19 Q. Okay. And you mentioned the Heller      20 study in a couple of places. You mentioned      21 several times that part of your plausibility      22 opinions involve the fact that talc has been      23 observed in the ovaries; correct?</p> <p>24 A. Can you show me? I'm sorry. I just      25 want to make sure.</p>	<p>1 that they did not find on their H&amp;E slides any      2 response -- any expected response to talc      3 particles.</p> <p>4 Do you remember that?</p> <p>5 A. I do remember that vaguely. Yes.</p> <p>6 Q. Did any of the studies that you cite in      7 that section for the proposition that talc has      8 been found in ovarian tissue, did any of those      9 find a reaction to talc in the ovaries?</p> <p>10 A. I don't believe the studies that have      11 found talc in the ovaries have all looked for      12 chronic inflammation. Some of them, if I'm      13 remembering correctly, I don't know if they all      14 looked histologically; but the ones that did, I      15 don't believe they had mentioned finding chronic      16 inflammation near the talc particles.</p> <p>17 But again, you know, depending on how long      18 that inflammatory response is going to be there,      19 depending how long that particular talc particle      20 has been there, you wouldn't necessarily expect      21 to still see it 20 years later.</p> <p>22 Q. Okay. In the Heller study, they looked      23 at ovarian tissue -- ovaries from one of their      24 subjects who had 1.7 or approximately      25 1.669 million particles per gram of wet weight by</p>

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<p>1 electron microscopy and found on hematoxylin and      2 eosin stain slides from the analyzed sections of      3 the tissue that no evidence of response to talc      4 such as foreign body giant cell reactions or      5 fibrosis in the tissue.      6 Is that consistent with the other studies      7 that have reported findings from H&amp;E have also      8 reported no response to talc or supposed talc      9 they found?      10 What is an alternative explanation for how      11 microscopists doing these sorts of studies might      12 find talc by TEM or SEM without any histologic      13 response --      14 MR. ROTMAN: Objection.      15 Q. -- to talc in the tissue?      16 A. Well, I think I addressed that a little      17 earlier. Again, I don't know -- we don't know      18 how long a chronic inflammatory response would be      19 there after a particular talc particle lands on      20 the ovary.      21 But the important thing would be that that      22 chronic inflammation, the initial chronic      23 inflammation, whenever that may be, however long      24 it is there, causes oxidative stress that induces      25 an oncogenic change in an ovarian cell or</p>	<p>1 MS. AHERN: What number are we on?      2 COURT REPORTER: Twenty-five.      3 MS. AHERN: Twenty-five.      4 MR. TISI: So 24 was --      5 MS. AHERN: We'll wait.      6 (Article entitled "The      7 relationship between perineal cosmetic talc      8 usage and ovarian talc particle burden"      9 marked Exhibit 25.)      10 A. I believe they went through standard      11 electron microscopy methods, which controls for      12 contamination.      13 BY MS. AHERN:      14 Q. How?      15 A. I don't know if it goes through the      16 whole -- but they're very careful in how they      17 handle tissue before they prep for electron      18 microscopy.      19 Q. Doctor, do you know where they got the      20 tissue from?      21 A. Yeah. It's listed.      22 Q. Did they collect the tissue themselves      23 from the patient in a particulate-free      24 environment and handle it with particulate-free      25 gloves in containers, or did they get it from</p>
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<p>1 fallopian tube cell, for that matter.      2 So -- and these are very small studies that      3 looked at histologic -- that looked      4 histologically for talc in these ovaries.      5 So, you know, I don't necessarily think -- I      6 don't think that you would have to find chronic      7 inflammation if you're looking at an ovary at a      8 particular point in time when we're talking about      9 long-term talc use from, you know, up to 20 years      10 ago or something.      11 Q. Well, if they're finding 1.7 million      12 particles per gram of wet tissue right then and      13 there, and their slides from that time period      14 don't show any response whatsoever to talc that      15 they would expect to see, what's an alternative      16 explanation?      17 A. An alternative explanation is that      18 there was chronic inflammation, and it has since      19 resolved.      20 Q. How about there might be contamination      21 of their samples with talc, which is ubiquitous      22 in many laboratories?      23 A. I believe they -- I have to look at the      24 study to -- do you have the study?      25 MR. ROTMAN: Thank you. What number?</p>	<p>1 hospital paraffin-embedded tissue?      2 If you look on Page 1508, "Ovarian tissue in      3 blocks was reparaftinized, rehydrated, blotted dry      4 and weighed, and then digested with reagents."      5 A. So I think these women were talc users.      6 I'm trying to find controls that they had ovaries      7 from -- if I remember correctly, they had ovaries      8 from fetal cases that did not show talc, if I      9 remember correctly. I'm trying to find that.      10 Yeah. "In addition, the ovaries of two      11 stillborn fetuses were analyzed as negative      12 controls."      13 Q. Does it say anything about where those      14 stillborn fetus ovaries came from and if they      15 were handled in the same hospital in the same way      16 that the parafinized blocks were handled?      17 A. If they didn't have a separate section      18 of their methods how they handled it, it would be      19 the same methodology.      20 Q. Well, assuming it's not contamination      21 and there's still no reaction to talc, another      22 alternative explanation might be that talc      23 doesn't cause chronic inflammation in the      24 ovaries.      25 A. But they didn't find talc in their</p>

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<p>1 negative controls, which were fetal females that      2 would never have been exposed to talc.      3 Q. Except for after the tissues were taken      4 from the fetuses and processed?      5 A. I'm just trying to find where they --      6 what they did.      7 Q. What I wonder and what I don't think is      8 in the paper, unless you can find it, is an      9 explanation for how the fetal ovaries were      10 obtained and processed.      11 Did they come from the same hospital      12 system --      13 A. It would be the same.      14 Q. -- from the laboratory so that any      15 contamination that occurred to those tissues      16 prior to the Heller group getting them was      17 accounted for?      18 Or did they purchase them separately through      19 a company or something else that handled them      20 differently from the hospital samples?      21 MR. ROTMAN: Objection.      22 A. If those were obtained differently, it      23 should have been in the methodology. So the fact      24 that it's not there, the next sentence after they      25 say, "In addition, the ovaries of two stillborn</p>	<p>1 something that would happen over days. Chronic      2 inflammation is generally longer, but it still      3 resolves.      4 Q. And are -- for instance, pelvic      5 inflammatory disease is -- the effects of pelvic      6 inflammatory disease can be seen by pathologists      7 for a very long time; correct?      8 A. You can see fibrosis. So...      9 Q. And one of the things that you      10 mentioned earlier is that talc can cause      11 fibrosis?      12 A. Talc can cause fibrosis. You get -- in      13 the ovary, however, you will get surface      14 fibrosis, generally, from the mesothelial cells      15 in the surface.      16 But, again, you're not always going to have      17 fibrosis with chronic inflammation, either.      18 Q. If it's chronic inflammation that is      19 significant enough to lead to a transformative      20 event, shouldn't you expect to see some evidence      21 of that chronic inflammation?      22 A. Well, we don't know how much chronic      23 inflammation is necessary to cause a carcinogenic      24 effect.      25 Q. By analogy, wouldn't you look at</p>
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<p>1 fetuses were analyzed as negative controls," that      2 is where, if it had been a different methodology      3 or different purchased ovarian cell blocks from      4 fetuses, which I have never -- anyway, it would      5 be -- it would be there. And it's not.      6 Q. Hmm. So my next question is: I had      7 asked you earlier if there was an alternative      8 explanation for why there's no tissue response      9 seen in this study to talc particles, and you      10 said it could be because the chronic inflammation      11 was there and not there at the time that they      12 looked at the H&amp;Es?      13 A. Yeah. I mean, you're looking at an      14 ovary at a very -- at one time point. So we      15 don't know how long those talc particles were      16 there. We don't know if -- how long -- we don't      17 know how long the chronic inflammation is there.      18 But the important thing is that the chronic      19 inflammation would cause an event to change to an      20 oncogenic phenotype, gene type.      21 Q. So chronic inflammation is, by      22 definition, chronic; correct? Doesn't just -- it      23 doesn't just resolve in a couple of days.      24 It's ongoing; is that correct?      25 A. It is -- acute inflammation would be</p>	<p>1 something like ulcerative colitis and colon      2 cancer since that seems to be a fairly      3 well-established association?      4 A. Yes. And as soon as patients are      5 diagnosed with ulcerative colitis and Crohn's      6 disease, they are carefully followed at the      7 beginning. We don't wait 20 years to start      8 following them. We know that, you know, the risk      9 is there. As soon as they're diagnosed, we know      10 there is a risk for increased cancer, so we start      11 surveying them.      12 Q. But there's massive evidence of      13 inflammation -- tissue-damaging inflammation in      14 ulcerative colitis; correct?      15 A. Not always massive, but there's chronic      16 inflammation.      17 Q. Throughout the entire GI tract or      18 bowel?      19 A. In -- it's not always the whole, but      20 yeah, there's chronic inflammation in the      21 intestines.      22 Q. There's nothing in the literature that      23 suggests that talc causes that kind of an      24 inflammatory reaction, is there?      25 A. That talc causes a chronic</p>

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<p>1 inflammation?</p> <p>2 Q. That talc causes that sort of chronic</p> <p>3 inflammatory reaction.</p> <p>4 A. Well, I showed you some excerpts where</p> <p>5 they mention lymphocytic and plasmacytic</p> <p>6 inflammation due to talc. We know that talc</p> <p>7 causes an acute inflammation. I know we weren't</p> <p>8 talking about acute inflammation, but we know it</p> <p>9 causes acute inflammation in the -- after a</p> <p>10 pleurodesis. And I'm sure you could have</p> <p>11 lymphocytes in plasma cells there too.</p> <p>12 Again, I don't think it's the -- sure. The</p> <p>13 amount and duration of chronic inflammation, I</p> <p>14 mean, would that increase the risk? But even a</p> <p>15 small amount of chronic inflammation for a</p> <p>16 relatively short period of time, I think it's</p> <p>17 plausible.</p> <p>18 And, again, this is all under the plausible</p> <p>19 thing that this would cause a mutagenic effect.</p> <p>20 Q. Can you name other chronic inflammatory</p> <p>21 conditions that are not associated with cancer?</p> <p>22 A. Chronic inflammatory conditions that</p> <p>23 are not associated with cancer? Well, I'm not</p> <p>24 sure we absolutely know every -- that a chronic</p> <p>25 inflammatory condition won't cause a cancer,</p>	<p>1 Q. Have you ever diagnosed a patient with</p> <p>2 a talc-related ovarian cancer?</p> <p>3 A. It's entirely possible that I have, but</p> <p>4 I have not used polarized light microscopy on</p> <p>5 ovarian tumors, so it's possible I have and</p> <p>6 didn't look for talc -- didn't look for talc.</p> <p>7 MR. KLATT: Objection. Nonresponsive.</p> <p>8 Q. My question was: Have you ever</p> <p>9 diagnosed a patient with a talc-related ovarian</p> <p>10 cancer, meaning you have said, "Your cancer is</p> <p>11 related to talc use"?</p> <p>12 A. Well, first of all, I wouldn't have</p> <p>13 said that if I'm not looking for talc.</p> <p>14 But secondly, in our pathology reports, even</p> <p>15 though we're thinking and looking at causation,</p> <p>16 we're not necessarily putting in our individual</p> <p>17 patient reports what caused their cancer.</p> <p>18 We're certainly putting the diagnosis</p> <p>19 together with their medical history and their --</p> <p>20 to kind of make all the pieces fit together, but</p> <p>21 we're not necessarily in every patient putting</p> <p>22 out a report on what causes their cancer.</p> <p>23 MR. KLATT: Objection. Nonresponsive.</p> <p>24 MS. AHERN: Objection. Nonresponsive.</p> <p>25 Q. I just want to know if you've ever</p>
<p style="text-align: center;">Page 315</p> <p>1 but -- so I'm not really sure. I'm not really</p> <p>2 sure what you're getting at.</p> <p>3 Q. Can you list five chronic inflammatory</p> <p>4 conditions?</p> <p>5 A. That don't cause --</p> <p>6 Q. Just list five chronic inflammatory</p> <p>7 conditions.</p> <p>8 A. Well, we have rheumatoid arthritis that</p> <p>9 increases risk of lymphomas. We have</p> <p>10 Helicobacter pylori infections that increase</p> <p>11 gastric cancer. We have the ulcerative colitis,</p> <p>12 Crohn's disease, that increase the risk of</p> <p>13 cancer. Agent exposures like asbestos that</p> <p>14 causes chronic inflammation and causes cancer.</p> <p>15 HPV infection causes cancer. I mean...</p> <p>16 Q. Can you name one that doesn't involve a</p> <p>17 virus or an underlying immune dysfunction?</p> <p>18 A. I named asbestos.</p> <p>19 Q. Asbestos.</p> <p>20 And was there another?</p> <p>21 A. Again, I don't know if we have all the</p> <p>22 data on potential carcinogens and whether or not</p> <p>23 they cause chronic inflammation for sure. I</p> <p>24 think that, you know, we're still getting that</p> <p>25 data.</p>	<p style="text-align: center;">Page 317</p> <p>1 actually diagnosed a patient with a talc-related</p> <p>2 ovarian cancer. It sounds like the answer is no.</p> <p>3 If it is, it's okay. I need an answer.</p> <p>4 A. I'm trying to answer your question.</p> <p>5 Honestly, it's entirely possible that I have.</p> <p>6 But have I specifically put in a patient's</p> <p>7 report, "This ovarian cancer was caused by talc,"</p> <p>8 no.</p> <p>9 Q. Thank you. That's all I was asking.</p> <p>10 What about at tumor boards? Do you attend</p> <p>11 tumor boards?</p> <p>12 A. I do.</p> <p>13 Q. Have you ever suggested in a tumor</p> <p>14 board meeting with other colleagues that a</p> <p>15 particular patient's ovarian cancer was caused by</p> <p>16 talc use?</p> <p>17 A. I've certainly discussed with</p> <p>18 oncologists and radiation oncologists about my</p> <p>19 recent work. Again, it's been only in the last</p> <p>20 year and a half that I have really done this deep</p> <p>21 dive in this literature.</p> <p>22 And I've certainly talked to radiation</p> <p>23 oncologists, oncologists about it at tumor boards</p> <p>24 in a way of sort of educating them about my</p> <p>25 findings, but we haven't discussed in the context</p>

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<p>1 of a particular patient.</p> <p>2 Q. And were these discussions with</p> <p>3 radiation oncologists, were these people that</p> <p>4 focused on -- if they focus on -- gynecologic</p> <p>5 malignancies? Were they more pulmonary? Is</p> <p>6 there a difference with radiologists in terms of</p> <p>7 specialty?</p> <p>8 A. There are some subspecialties. In this</p> <p>9 one, they were more general radiation</p> <p>10 oncologists.</p> <p>11 Q. Okay.</p> <p>12 MS. AHERN: How much time do we have?</p> <p>13 THE VIDEOGRAPHER: Fifteen minutes.</p> <p>14 MS. AHERN: I'm going to turn it over</p> <p>15 to my colleagues so they have an opportunity to</p> <p>16 ask questions. Thank you very much. I</p> <p>17 appreciate it.</p> <p>18 THE WITNESS: Thank you.</p> <p>19 MR. KLATT: How much time do we have?</p> <p>20 We're at 6:37 right now.</p> <p>21 Are you ready for me to continue?</p> <p>22 CROSS-EXAMINATION</p> <p>23 BY MR. KLATT:</p> <p>24 Q. Dr. Kane, are you ready to continue?</p> <p>25 A. Yes.</p>	<p>1 asbestos in it.</p> <p>2 Are you choosing to believe the plaintiffs'</p> <p>3 asbestos experts over Ms. Pier's testimony?</p> <p>4 MR. TISI: Objection.</p> <p>5 A. Again, I think these were pieces of</p> <p>6 information for me. I wasn't relying on her --</p> <p>7 the exhibit from her testimony for my general</p> <p>8 causation. I wasn't -- and I didn't see</p> <p>9 Dr. Longo's reports until very late in my process</p> <p>10 from what I recall.</p> <p>11 It's interesting information for me. It's</p> <p>12 informative in that if the talcum powder products</p> <p>13 cause [sic] asbestos, that certainly lends</p> <p>14 significance to plausibility. But I'm --</p> <p>15 MR. ROTMAN: Do you want to reread your</p> <p>16 answer there? I think you misspoke.</p> <p>17 THE WITNESS: Okay. Sorry.</p> <p>18 A. Yes. I did. If the talcum powder</p> <p>19 contains asbestos, that certainly adds to the</p> <p>20 plausibility. But I'm not opining on whether or</p> <p>21 not talcum powder products contain asbestos.</p> <p>22 Q. And you wouldn't have the expertise to</p> <p>23 decide that Dr. Longo's testimony about asbestos</p> <p>24 in talc is more credible than Ms. Pier's</p> <p>25 testimony about asbestos in talc, do you?</p>
<p>1 Q. Can you hear me okay?</p> <p>2 A. Yes.</p> <p>3 Q. Yes. Dr. Kane, my name is Mike Klatt,</p> <p>4 and I represent a company called Imerys Talc</p> <p>5 America in this case.</p> <p>6 Before this lawsuit, have you ever heard of</p> <p>7 Imerys Talc America?</p> <p>8 A. I don't believe I had, no.</p> <p>9 Q. Do you know what Imerys Talc America</p> <p>10 does?</p> <p>11 A. From my understanding, they mine talc,</p> <p>12 and they supply -- they're the talc -- one of the</p> <p>13 talc suppliers for Johnson &amp; Johnson.</p> <p>14 Q. You said earlier you reviewed an</p> <p>15 exhibit of Julie Pier's deposition.</p> <p>16 Do you know who Julie Pier is?</p> <p>17 A. I know she was a designated</p> <p>18 representative. I don't know if it was for J&amp;J</p> <p>19 or for Imerys off the top of my head.</p> <p>20 Q. Ms. Pier works at Imerys, and she's an</p> <p>21 expert microscopist and at analyzing talc for any</p> <p>22 extraneous substances like asbestos.</p> <p>23 She testified that the evidence you looked</p> <p>24 at did not indicate in any way that talc that</p> <p>25 ended up in Johnson &amp; Johnson's baby powder had</p>	<p>1 A. I have a, I would say, cursory</p> <p>2 knowledge of how they would test for asbestos. I</p> <p>3 couldn't say that I am an expert in the methods</p> <p>4 that they use to detect asbestos.</p> <p>5 Q. But my specific question is: You don't</p> <p>6 have the expertise to determine that Dr. Longo's</p> <p>7 testimony about asbestos and talc is more</p> <p>8 credible with or more believable or more</p> <p>9 scientifically valid or less scientifically valid</p> <p>10 than Ms. Pier's testimony about asbestos and</p> <p>11 talc; correct?</p> <p>12 That's my question.</p> <p>13 A. Again, it's pieces of information for</p> <p>14 me. I don't know anything, really, about</p> <p>15 Dr. Longo versus Ms. Pier. I just have seen the</p> <p>16 exhibit from Ms. Pier's testimony and Dr. Longo's</p> <p>17 report, but I don't have more information nor</p> <p>18 have I really sought it out about their</p> <p>19 credentials. I was just using it as pieces of</p> <p>20 information.</p> <p>21 Q. But again my question is: You have no</p> <p>22 ability or expertise on your own to judge whether</p> <p>23 Ms. Pier's testimony that there's not asbestos in</p> <p>24 talc is correct or Dr. Longo's testimony is</p> <p>25 correct. That's not an area of your expertise;</p>

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<p>1 correct?</p> <p>2 A. It -- I wouldn't say I'm an expert in 3 that area.</p> <p>4 Q. You mentioned earlier in response to 5 Ms. Ahern's questions, you talked about heavy 6 metals.</p> <p>7 Are you aware that IARC has not singled out 8 a single heavy metal as a cause of ovarian 9 cancer?</p> <p>10 A. Yes. I have seen that. I have 11 reviewed the IARC monograph on heavy metals, and 12 I'm aware.</p> <p>13 But, again, it's another sort of piece of 14 the plausibility puzzle. If we -- we know that 15 some of them are either listed as carcinogens or 16 probable carcinogens. If they're in the talcum 17 powder product, that's just another piece of the 18 biological plausibility puzzle. And I --</p> <p>19 Q. Well, is it your -- I'm sorry. I 20 didn't mean to cut you off.</p> <p>21 A. No. Sorry.</p> <p>22 Q. Is it your testimony that if something 23 is considered a carcinogen for one organ system 24 by IARC, that it's capable of causing cancer in 25 all organ systems?</p>	<p>1 at the end of the answer before you started your 2 next question.</p> <p>3 A. So I'm aware that they're in these 4 things. What I'm looking at is a product that's 5 used frequently and for -- in a lot of women for 6 a long duration of time. So their exposure -- if 7 they are in the talcum powder, their exposure to 8 those heavy metals would be greater than the 9 exposure they're getting in the environment.</p> <p>10 Q. Those same, exact heavy metals are in 11 drinking water, bottled water, food, and 12 multivitamins that people take every single day, 13 and there's no evidence that they cause ovarian 14 cancer; correct?</p> <p>15 A. There has not been a link with heavy 16 metals to ovarian cancer specifically as of yet.</p> <p>17 Q. And there's no evidence you're aware of 18 that the tissue levels of any heavy metals are 19 higher in talc users than in women who never used 20 talc; correct?</p> <p>21 A. I don't -- I'm not aware of that study 22 being done.</p> <p>23 Are you talking tissue levels?</p> <p>24 Q. Blood levels --</p> <p>25 A. Blood levels.</p>
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<p>1 A. As I've testified several times here 2 today, I think different tissues respond in 3 different ways to different carcinogens. So I 4 would not make a blanket statement that a 5 carcinogen in one site will definitely cause 6 cancer in another site.</p> <p>7 However, having carcinogens, known 8 carcinogens in a product, it can add to the 9 biological plausibility. And we're not talking 10 about these heavy metals sort of in the 11 environment. I mean, these are -- there's 12 evidence that they are in a product that's used 13 regularly and frequently.</p> <p>14 Q. Are you -- are you aware that the same, 15 exact heavy metals are in bottled drinking water?</p> <p>16 A. So, again, I don't know what the levels 17 of these heavy metals are in drinking water. I 18 know that they are found in the environment 19 commonly.</p> <p>20 Q. Are you aware they're in foods?</p> <p>21 A. I'm aware that they are in the 22 environment and foods regularly. Yes. But --</p> <p>23 Q. Are you aware they're in multivitamins?</p> <p>24 MR. ROTMAN: Wait. Wait. 25 I was hearing a "but" and not a period</p>	<p>1 -- tissue levels. Anything you want. 2 You're -- there's no medical or scientific 3 evidence that you would tell this court that the 4 levels of heavy metals in women who use talcum 5 powder in the genital area are higher than women 6 who have never used talcum powder?</p> <p>7 A. I'm not aware of studies that have been 8 done that have looked at the levels of those 9 heavy metals in ovarian tissue or blood levels.</p> <p>10 Q. Earlier you mentioned there was a study 11 about changing gene expression in the presence of 12 talc in mesothelial cells?</p> <p>13 A. Yes.</p> <p>14 Q. The mere fact that you have changing 15 gene expression in no way implies something is 16 carcinogenic; correct?</p> <p>17 A. It -- it's evidence that it's changing 18 gene expression within those cells, and --</p> <p>19 Q. If -- I'm sorry. Go ahead.</p> <p>20 A. And the genes in that study that had 21 increased expression are involved in the 22 inflammatory -- are pieces in the inflammatory 23 response.</p> <p>24 Q. You're aware that many of those genes 25 in that study were antioxidant genes and</p>

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<p>1 anti-inflammatory genes that were elevated; 2 correct? 3 A. They can regulate or deregulate, and I 4 think it's interesting -- let's say that they 5 were antioxidant -- they were producing 6 antioxidant enzymes. I think that is evidence 7 that it's trying -- that the cell is trying to 8 respond and is trying to prepare itself for an 9 insult, an inflammatory insult. Otherwise, why 10 would that gene be expressed? 11 So, I mean, there's increased and decreased 12 regulation. 13 Q. But, Dr. Kane, you're aware that 14 strenuous exercise can increase gene expression 15 of prooxidants, antioxidants, proinflammatory, 16 anti-inflammatory proteins; correct? 17 A. Strenuous exercise can increase 18 antioxidants in proinflammatory, 19 anti-inflammatory proteins. 20 But, again, I'm opining about a product that 21 someone is going to be using regularly with 22 frequency over a long period of time. 23 Q. You're aware that -- 24 A. It just adds to the -- I'm not -- you 25 know, I don't have an opinion about whether or</p>	<p>1 MR. KLATT: Can we mark that? 2 MR. ROTMAN: Can we get a time check? 3 THE VIDEOGRAPHER: 6:30. 4 MR. ROTMAN: Thank you. 5 (Article entitled "Pycnogenol 6 reduces Talc-induced Neoplastic 7 Transformation in Human Ovarian Cell 8 Cultures" marked Exhibit 26.) 9 MS. AHERN: That's 26. 10 Q. Referring to Exhibit 26, Dr. Kane, is 11 this the Buz'Zard study you were mentioning 12 earlier? 13 A. Yes, this is it. 14 Q. And if you'll flip over to Page 3 -- 15 excuse me, 582, Figure 3, do you see Figure 3 16 is -- 17 MR. ROTMAN: Can I have a copy of that, 18 please? 19 MR. KLATT: I'm sorry? 20 MR. ROTMAN: I'm waiting for a copy of 21 that. 22 MR. KLATT: Oh. Yes. We do provide 23 copies. 24 MR. ROTMAN: This is Exhibit No. 1? 25 THE WITNESS: I'm sorry. Which table?</p>
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<p>1 not those heavy metals are in talc. I've looked 2 at some evidence that they are there, but I don't 3 have an opinion that they're actually in talc. 4 It's just another piece of evidence, again, for 5 the biological plausibility. 6 Q. Well, you're not saying that people who 7 regularly engage in chronic exercise, chronic 8 strenuous exercise, for a long period of time are 9 at increased risk of cancer because they have 10 increased gene expression, are you? 11 A. Well, there hasn't been epidemiologic 12 evidence that is consistent that people who do 13 routine strenuous exercise get cancer. 14 Q. The Buz'Zard study you cited, that 15 actually showed that talc -- increasing doses of 16 talc decreased release of reactive oxygen species 17 from ovarian cells, not increased it; correct? 18 A. I believe it was different -- I would 19 have to look at the study, but it was over 20 different time periods. It fluctuated. 21 Q. The highest level of reactive oxygen 22 species in the Buz'Zard study was the group of 23 cells that had no talc applied at all; correct? 24 A. I'd have to re-review the study. 25 Q. Let's --</p>	<p>1 MS. AHERN: Twenty-six. 2 BY MR. KLATT: 3 Q. Figure 3. Page 582. 4 MR. ROTMAN: What exhibit are we on? 5 COURT REPORTER: Twenty-six. 6 MR. ROTMAN: Thank you. 7 BY MR. KLATT: 8 Q. And you see Figure 3 is "ROS." 9 That stands for reactive oxygen species? 10 A. That's -- 11 Q. And, by the way, ROS are generated by 12 every cell of the body every day, 24 hours a day; 13 correct? 14 A. Reactive -- you do see it in daily cell 15 life. But, again, I'm talking about an 16 additional exposure, an agent that that is being 17 applied in addition to what you're seeing on -- 18 basically the cell has, as we just discussed, 19 they have ways of mitigating reactive oxygen 20 species. 21 The cell can increase their antioxidant 22 enzymes, but at some point, they can get 23 overloaded. So if you're giving it a higher dose 24 at a higher frequency than those systems can 25 handle, you're going to have an increased risk of</p>

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<p>1    mutagenesis. 2    Q. Well, let's look at what Buz'Zard found 3    when talc was applied to surface ovarian cells. 4    Do you see that? That's Figure 3A up at the 5    top? 6    A. A, up at the top. Yes. 7    Q. And you'll agree with me, you see on 8    the Y axis it says "Percentage of reactive oxygen 9    species generation in OSE2a cells"; correct? 10   A. Yes. 11   Q. That's ovarian surface epithelial 12   cells; correct? 13   A. Yes. 14   Q. And you'll see at the zero talc level 15   on the X axis -- 16   A. Mm-hmm. 17   Q. -- that had 100 percent talc -- excuse 18   me -- a 100 percent reactive oxygen species 19   generation at all three time periods; correct? 20   A. That is correct. And -- 21   Q. And when talc was applied? 22   MR. ROTMAN: Wait. Wait. 23   Did you finish your answer? 24   A. Well, we were just talking about how 25   cells can have innate ROS generation.</p>	<p>1    generation for each talc microgram. 2    Q. Do you see in the far right column, 3    they applied 200 micrograms of hydrogen peroxide? 4    A. Yes. 5    Q. And that resulted in a 200 percent 6    increase in reactive oxygen species during those 7    time periods; correct? 8    A. That is what it says. Yes. 9    Q. And that's their positive control; 10   correct? 11   A. Let me just double-check. 12   If I'm remembering the study correctly, yes, 13   you are -- you are right. 14   Q. People gargle with hydrogen peroxide; 15   correct? 16   A. They shouldn't. 17   Q. Well, you know, it's allowed on the 18   bottle. 19   You know that; correct? 20   A. If you're telling me they gargle with 21   it, that's fine. 22   Q. Well, they put it on cuts; right? 23   A. They shouldn't put it on cuts. It's 24   actually -- 25   Q. It's sold for that, isn't it?</p>
<p style="text-align: center;">Page 331</p> <p>1    Q. And this graph shows that as you 2    applied increasing doses of talc, the level of 3    generation of reactive oxygen species in the 4    ovarian cells went down. 5    It didn't go up; correct? 6    A. Well, it goes up at -- what's the 50 -- 7    the 50 micrograms per milliliter. It goes up at 8    that dose at the 120 hour, and then it goes up at 9    the 200 microgram level. 10   Q. That's not talc, is it? 11   A. I'm sorry. I'm looking at -- I'm 12   looking at -- it says "Talc micrograms per 13   milliliter," and then it lists the different 14   hours on the right; that they're color-coded to 15   the different hours. 16   Q. And 17 out of the 18 measurements they 17   took when talc is applied to ovarian cells showed 18   the ovarian cells generated less reactive oxygen 19   species than no talc at all; correct? 20   A. And I -- 21   Q. Is that correct? 22   A. It looks like at different periods of 23   time at the 100 micrograms and 500, there was 24   less than the lower. But I'm not sure what the 25   threshold dose would be for optimal ROS</p>	<p style="text-align: center;">Page 333</p> <p>1    A. I think most MDs would tell you that 2    it's probably better not to use hydrogen peroxide 3    on open cuts because it can cause a pretty severe 4    reaction. 5    Q. You're aware that it's sold over the 6    counter in stores every day for -- as an 7    antiseptic? 8    A. Talcum powder is sold for everyday use 9    on babies. 10   Q. So are you telling us that hydrogen 11   peroxide now causes cancer? 12   A. I'm saying that it will release ROS 13   species generation. 14   Q. Far more than talc; correct? 15   A. Based on this study, it appears that 16   way. 17   Q. And you -- 18   A. This one study. 19   Q. You agree with me this shows, as you 20   apply talc, reactive oxygen species in ovarian 21   cells decreases. 22   It doesn't increase at 17 out of 18 time 23   points; correct? 24   A. They're -- I will agree with you, 25   except there is a time point where it is</p>

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<p>1 increased. And I don't know -- my caveat is I      2 don't know where the threshold would be where the      3 ROS would stop being generated.</p> <p>4 Q. Is aspirin approved by any      5 pharmaceutical company or recommended by any      6 medical organization for prevention of ovarian      7 cancer?</p> <p>8 A. That is not on the label description.</p> <p>9 Q. If aspirin prevented ovarian cancer,      10 don't you think it would be marketed for that      11 purpose?</p> <p>12 MR. TISI: Objection.</p> <p>13 MR. ROTMAN: Objection.</p> <p>14 A. I'm sure it may be after years of FDA      15 red tape and approval, but the literature --      16 again, I've said the literature is not as beefy      17 as the epi data when we're looking at aspirin and      18 NSAIDs.</p> <p>19 NSAID, in particular, is not as consistent.      20 The aspirin data does appear to be consistent in      21 lowering the risk, but there are not a lot of      22 studies looking at this yet.</p> <p>23 Again, though, just a piece of the puzzle      24 for a biologic plausibility.</p> <p>25 Q. Well, certainly, we're not at the point</p>	<p>1 A. I have to look at the studies. There      2 might be one where it wasn't statistically      3 significant, but I think the majority of the ones      4 that looked at aspirin use showed a decreased      5 risk of ovarian cancer.</p> <p>6 Q. Are you -- are you a member of the      7 International Society of Gynecologic      8 Pathologists?</p> <p>9 A. I don't think I'm a member currently.      10 No.</p> <p>11 Q. Have you ever been?</p> <p>12 A. I believe so.</p> <p>13 Q. It's not on your CV.</p> <p>14 A. Okay. I'm not currently. I know that.</p> <p>15 Q. Are you a member of the American      16 Society of Clinical Pathology?</p> <p>17 A. I actually am.</p> <p>18 Q. It's not on your CV.</p> <p>19 A. Okay. That should be updated, then.</p> <p>20 Q. Have you ever been a member of any      21 working group or organization on the      22 classification of female reproductive organ      23 tumors?</p> <p>24 A. No. I can't -- no.</p> <p>25 Q. You mentioned the Surgeon General's</p>
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<p>1 for aspirin and ovarian cancer that we are, for      2 example, with aspirin in terms of cardiovascular      3 risk; correct?</p> <p>4 A. I would agree with that sentiment.</p> <p>5 Q. And doctors and medical organizations      6 have recommended aspirin for reduction of      7 cardiovascular risk; correct?</p> <p>8 A. That's correct. Although the dosage      9 has -- as of late, they're kind of parsing out      10 the -- they're reevaluating what dosages, but      11 you're correct.</p> <p>12 Q. And you can't cite a single medical      13 organization that at this point in time says the      14 evidence that aspirin reduces ovarian cancer is      15 sufficient that women should take it on a regular      16 basis to reduce ovarian cancer; correct?</p> <p>17 A. Well, I think I've said there aren't      18 that many studies yet. It's only -- that I'm      19 aware of, there are only a handful. They've been      20 consistent with aspirin. Not so much with NSAID.      21 That's, I think, as far as the evidence takes us      22 as this point.</p> <p>23 Q. There's actually studies showing that      24 chronic aspirin ingestion doesn't decrease      25 ovarian cancer risk; correct?</p>	<p>1 report in 1964. You're aware that when that came      2 out about smoking, there were numerous studies in      3 the literature at that point in time showing that      4 the chemicals in cigarette smoke actually damaged      5 DNA and resulted in cancer; it wasn't based just      6 on epidemiology?</p> <p>7 A. I think epidemiology -- my point was      8 that the epidemiology was the sort of first --      9 there were pathologists that had noticed on      10 autopsies in patients that smoked -- it was      11 actually pathologists and a surgeon in the early      12 years -- that had noticed some changes, some      13 squamous metaplastic changes.</p> <p>14 But it was really the epi data that sort of      15 drove the research on smoking and tobacco      16 initially. But, again, there were some studies      17 that had shown some pathologic changes in      18 smokers. That's true.</p> <p>19 Q. You're aware that the cohort studies,      20 the hospital-based case-control studies, and the      21 population-based case-control studies all      22 uniformly showed that smoking increased the risk      23 of lung cancer; correct?</p> <p>24 A. That's correct.</p> <p>25 Q. And that's not true for talc and</p>

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<p>1 ovarian cancer; correct?</p> <p>2 A. Well, I have some issues with the</p> <p>3 cohort studies.</p> <p>4 Q. I know that.</p> <p>5 But my statement is true; correct?</p> <p>6 A. But I think it's relevant because the</p> <p>7 cohort studies, I don't believe, followed</p> <p>8 patients for a long enough time.</p> <p>9 The Nurses' Health Study only asked about</p> <p>10 talcum powder use once in 1982, so there's</p> <p>11 certainly room for misclassifications of users as</p> <p>12 never users.</p> <p>13 And some of -- some of -- again, there's</p> <p>14 smaller numbers because it's a -- it's a cohort</p> <p>15 study.</p> <p>16 Q. You're aware that the National Cancer</p> <p>17 Institute doesn't agree with you on that, aren't</p> <p>18 you?</p> <p>19 A. I have seen the NCI website. I</p> <p>20 certainly considered what they say about it. I</p> <p>21 don't know if they have done the same type of</p> <p>22 analysis as I've done. I don't believe it's on</p> <p>23 their website what methodology they used and what</p> <p>24 literature they reviewed.</p> <p>25 So I'm aware of what they've stated. But,</p>	<p>1 that one statement.</p> <p>2 Go ahead.</p> <p>3 MR. ROTMAN: If you want to do that,</p> <p>4 that's fine.</p> <p>5 BY MR. KLATT:</p> <p>6 Q. That draft -- Health Canada issued a</p> <p>7 draft assessment that's undergoing a 60-day</p> <p>8 public comment period; correct?</p> <p>9 A. That's true.</p> <p>10 Q. And then they have up to two years to</p> <p>11 decide whether to take any action or no action at</p> <p>12 all; correct?</p> <p>13 A. Well, there's two pieces of that. From</p> <p>14 my understanding is that they've already done the</p> <p>15 scientific. They've already done the literature</p> <p>16 review. They've already done their Bradford Hill</p> <p>17 analysis, and they've come to the conclusion that</p> <p>18 they've come to.</p> <p>19 And then there's the public commentary. And</p> <p>20 then there's the regulatory aspect of it.</p> <p>21 Now, I am -- I would not claim to be an</p> <p>22 expert in regulatory. I know we have regulatory</p> <p>23 experts that are coming on. But in -- from my</p> <p>24 understanding, the regulatory aspect is different</p> <p>25 than the scientific aspect.</p>
<p style="text-align: center;">Page 339</p> <p>1 you know, I've still done this extensive review</p> <p>2 that I'm not sure they did to come to my</p> <p>3 conclusion.</p> <p>4 Q. You honestly don't know what the NCI</p> <p>5 did in terms of review to come to their</p> <p>6 conclusion, do you?</p> <p>7 A. They didn't state what they did, so I</p> <p>8 do not know. So that would -- but that's</p> <p>9 something that I'm thinking about when I'm taking</p> <p>10 into consideration.</p> <p>11 Q. And you are aware that they just</p> <p>12 updated their statement that the evidence does</p> <p>13 not support a link between talc and ovarian</p> <p>14 cancer in January 2019, the same month we're</p> <p>15 sitting here today?</p> <p>16 A. I don't know if I've gone to the NCI</p> <p>17 website this month.</p> <p>18 But I'm also aware of Health Canada that</p> <p>19 came out and did -- and we know what the</p> <p>20 methodology and literature they -- they spelled</p> <p>21 it out very clearly what their methodology was,</p> <p>22 what literature review they did, and they came to</p> <p>23 the same conclusion that I did.</p> <p>24 MR. ROTMAN: Off the record, Mike?</p> <p>25 MR. KLATT: Let me just follow up on</p>	<p style="text-align: center;">Page 341</p> <p>1 MR. ROTMAN: Mike, you're done? I just</p> <p>2 want to --</p> <p>3 MR. KLATT: I'm through.</p> <p>4 MR. ROTMAN: I just want to go off the</p> <p>5 record.</p> <p>6 We're done with seven hours.</p> <p>7 MR. KLATT: Yes. I'm done.</p> <p>8 MR. TISI: Let's take a minute.</p> <p>9 THE VIDEOGRAPHER: Off the record,</p> <p>10 6:31 p.m.</p> <p>11 (A recess was taken.)</p> <p>12 THE VIDEOGRAPHER: Back on the record,</p> <p>13 6:40 p.m.</p> <p>14 CROSS-EXAMINATION</p> <p>15 BY MR. ROTMAN:</p> <p>16 Q. Dr. Kane, I know it's been a long day</p> <p>17 for you, but I'm going to ask you a few</p> <p>18 questions. I will be brief.</p> <p>19 A. Okay.</p> <p>20 Q. At one point today, you were asked some</p> <p>21 questions by Attorney Ahern about certain</p> <p>22 negative studies on inflammation, and she</p> <p>23 mentioned Bonovast 2005 and Ni 2012, which she</p> <p>24 asked you about.</p> <p>25 Do you recall that?</p>

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<p>1 A. Yes. 2 Q. She did not show you those studies, did 3 she? 4 A. I don't believe I saw them. 5 Q. Are you able to agree with her 6 characterization that these were negative studies 7 without having -- without looking at them? 8 A. I should have asked for them and had 9 them in front of me while asking questions. 10 Q. Now, you were asked questions -- 11 A. I mean answering questions. 12 Q. -- throughout the day about 13 inflammation as a biologically plausible 14 mechanism for explaining talc causing ovarian 15 cancer in light of the epi study findings. 16 A. Yes. 17 Q. You were also asked questions about 18 cigarette smoking at various times throughout the 19 day? 20 A. Yes. 21 Q. Does cigarette smoking have an 22 inflammatory effect? 23 A. Yes. 24 Q. What is the -- 25 A. It does cause chronic inflammation.</p>	<p>1 just strike that. 2 You were asked questions about surgical 3 gloves and surgical-grade talc on surgical 4 gloves. 5 A. Yes. 6 Q. Do you recall that? 7 A. Yes. 8 Q. And I think you were asked if you were 9 aware of any studies linking the use of talcum 10 powder on surgical gloves with the occurrence of 11 ovarian cancer. 12 Do you recall that? 13 A. Yes. 14 Q. Is there a difference, a notable 15 difference, between talcum powder on surgical 16 gloves and the talcum powder products in perineal 17 use that, regardless of the constituent of the 18 powder, that you would want to point out? 19 MR. KLATT: Objection. Form. 20 MS. AHERN: Same. 21 A. So a patient's exposure to surgical 22 gloves are going to be infrequent and not of long 23 duration. It's not the same type of exposure as 24 regular and frequent application of perineal 25 talcum powder that we're seeing in the epi data.</p>
<p>1 Q. You were also asked questions about 2 heavy metals being present in food and water and 3 vitamins; correct? 4 A. I remember. Yeah. 5 Q. Do -- what is different between those 6 circumstances and the situation that we have been 7 discussing all day today involving talcum powder? 8 A. With talcum powder, we do have the epi 9 data that are consistent and show an increased 10 risk of ovarian cancer with talcum powder use. 11 Q. And with respect -- you were asked some 12 questions in relation to the Buz'Zard study about 13 hydrogen peroxide and the reactive oxygen species 14 reaction? 15 A. Yes. 16 Q. Are you aware of any evidence that 17 hydrogen peroxide -- the effect of hydrogen 18 peroxide in the female genital tract? 19 A. I'm not aware that women routinely use 20 hydrogen peroxide in the female genital tract. 21 Q. And is there anything in particular 22 about the -- that part of the anatomy that where 23 certain agents, exposure to certain agents, would 24 raise any particular concerns -- strike that. 25 I think that was a bad question, so I'll</p>	<p>1 MR. ROTMAN: No further questions. 2 It's 6: -- 3 (Discussion off the record.) 4 MR. ROTMAN: You're right. 5 BY MR. ROTMAN: 6 Q. I have some questions for you about 7 your testimony on the Harlow paper. 8 A. Okay. 9 Q. Can you pull that out in front of you, 10 which was Exhibit 20? 11 A. Okay. 12 Q. Can you turn to Table 3. 13 A. Okay. 14 Q. And do you recall that you were asked 15 questions about dose-response in this study? 16 A. Yes. 17 Q. And do you recall that you were 18 specifically asked questions about this Table 3? 19 A. Yes. 20 Q. Could you look at the middle part of 21 Table 3, at the column with "adjusted odds 22 ratios"?</p> <p>23 A. Yes. 24 Q. What can -- what do you observe with 25 respect to the adjusted odds ratio as the -- as</p>

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<p>1 the -- as the number of applications goes from      2 less than 1,000 to greater than 10,000?      3 A. The adjusted ORs go from -- the null,      4 1.0 at none, 1.4 at less than 1,000, to 1.7 at      5 greater than 10,000.      6 Q. And so what, just looking at the      7 adjusted odds ratio, what --      8 A. It's an increase with increased --      9 Q. -- what is your takeaway?      10 A. So it does show an increased odds ratio      11 with increased applications.      12 The confidence intervals do include the      13 null, but they're -- the higher end, it's higher      14 confidence interval at the upper end.      15 And it's not very far from the null on the      16 lower end.      17 And it, in fact, includes -- it's 1.0 at      18 greater than 10,000.      19 Q. And so for the 1,000 to 10,000      20 applications, the lower bound of the confidence      21 interval is .9?      22 A. Correct.      23 Q. And how close is that to being a      24 statistically significant finding?      25 A. Very close.</p>	<p>1 A. Yes.      2 Q. And this is -- this is in the      3 "Discussion" section of the paper; is that right?      4 A. Yes.      5 Q. And do you see in the paragraph that      6 I'm pointing to that begins with "Our study"?      7 A. Yes.      8 Q. Could you read into the record and      9 comment on the last sentence in that paragraph.      10 A. "Daily versus less-than-daily talc use      11 and talc use for more than ten years versus less      12 than ten years were associated with greater risk      13 for ovarian cancer."      14 Q. And can you comment on that?      15 A. So that does show a trend for a      16 dose-response.      17 MR. ROTMAN: Okay. So I have 6:48.      18 You've got eight minutes.      19 RECROSS-EXAMINATION      20 BY MR. KLATT:      21 Q. That Harlow study you were just looking      22 at --      23 A. Yeah.      24 Q. -- is that the 1992 Harlow study?      25 A. It's the 1992 from Exhibit 20.</p>
<p style="text-align: center;">Page 347</p> <p>1 Q. And can you also take a look at the      2 discussion on that page in the left-hand column      3 in the paragraph that begins with "We also      4 examined"?</p> <p>5 A. Okay.</p> <p>6 Q. Is there a discussion in that paragraph      7 concerning the author's discussion of      8 dose-response?</p> <p>9 A. Yeah. There's a sentence that states,      10 "The categorical analysis showed that relative to      11 nonusers, the risk was greatest in women who      12 applied talc at least once per day. When years      13 of use was included as a continuous variable, the      14 test for linear trend was 3.32, p-value of .07.      15 "The categorial analysis show that relative      16 to nonusers, women who applied talc for more than      17 ten years were at a 60 percent greater risk for      18 ovarian cancer. Likewise, perineal applications      19 of talc early in life, before age 20, or      20 applications within six months of diagnosis      21 reference age for controls produced the stronger      22 ORs."</p> <p>23 Q. And I'd like to also call your      24 attention to the page 24 in the right-hand      25 column.</p>	<p style="text-align: center;">Page 349</p> <p>1 Q. And can you look on the last page of      2 this study, the page where the article ends and      3 the reference begins.      4 Did Harlow find the strength of association      5 between genital use of talc and ovarian cancer      6 was strong or weak?      7 A. So they use -- they say, "Because the      8 overall association between genital use of talc      9 and ovarian cancer remains weak."      10 And, again, "weak" is sort of a relative.      11 I've seen weak to moderate with this odds ratio.      12 And this is also 1992.      13 MR. KLATT: Object. Nonresponsive.      14 Q. I'm simply asking you, Dr. Kane, does      15 Harlow say strength of association between      16 ovarian cancer and talc use is strong or weak?      17 A. Well, I'm putting it in context. He      18 states -- I agree with you that's what the words      19 say, but I'm putting it in context in that "weak      20 to moderate" is used amongst epidemiologists for      21 this level of overall risk.      22 And this is 1992, so there wasn't the      23 subsequent studies that have gone on that show      24 consistent, similar overall risk odds ratio.      25 Q. And would it be correct that the</p>

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<p>1 statement that I asked you to read says in full,      2 "Because the overall association between genital      3 use of talc and ovarian cancer remains weak, it      4 is unlikely that this exposure disease pathway is      5 the principal one involved in ovarian cancer      6 etiology"?</p> <p>7 Is that what Harlow said?</p> <p>8 A. That's what it states. But, again,      9 that is 1992. This is the very beginning of the      10 epi data looking at this exposure and ovarian      11 cancer.</p> <p>12 MR. KLATT: Object and move to strike      13 everything after "That's what it says."</p> <p>14 Q. And, by the way, the odds ratio that      15 Harlow found overall was 1.5.</p> <p>16 And that's even a little higher than the      17 odds ratios the more recent meta-analyses have      18 shown; correct?</p> <p>19 A. So --</p> <p>20 Q. So they're even weaker than Harlow.</p> <p>21 A. I'm sure some epidemiologists might      22 take -- I'm not -- but, again, I've seen, even      23 with 1.3 and 1.4, epidemiologists refer to that      24 as "moderate."</p> <p>25 So I don't know if it's semantics, but it's</p>	<p>1 element of recall bias in case-control studies,      2 but the authors are aware. Many of them talk      3 about that and discuss why they feel recall bias      4 wasn't an explanation.</p> <p>5 And, again, we're talking about multiple      6 studies over numerous populations over different      7 periods of time, most of them well before the      8 general public knew about an association between      9 talcum powder and ovarian cancer.</p> <p>10 And even further, the fact that there's a      11 strong association in the literature with serous      12 invasive cancer would argue against a recall bias      13 because the lay public is not knowledgeable about      14 the histologic subtypes of epithelial ovarian      15 carcinoma.</p> <p>16 Q. Let me ask you this, Dr. Kane: We      17 lawyers, before we have to go to trial, like to      18 know if the prospective jurors have already made      19 up their mind about the case.</p> <p>20 Do you know if in any of these case-control      21 studies where the women who had ovarian cancer,      22 were they asked before they entered the study,      23 "Do you have a preconceived notion about what      24 caused your ovarian cancer?"</p> <p>25 A. I'm not aware of a case-control design</p>
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<p>1 1.3. It's a 30 percent increased risk. In this      2 case, 1.5, a 50 percent increase in risk. And in      3 a rare disease like ovarian cancer, that's      4 significant.</p> <p>5 Q. And Harlow calls a 1.5 odds ratio weak;      6 correct?</p> <p>7 A. That's what he says in this 1992 paper.</p> <p>8 Q. And you'd agree with me the more recent      9 meta-analyses of talc and ovarian cancer have a      10 lower odds ratio than 1.5?</p> <p>11 A. They seem to be between 1.3 and 1.4,      12 but the important thing to me is the consistency.</p> <p>13 Q. And you're aware that epidemiologists      14 say with case-control studies that odds ratios in      15 the range of 1.0 to 1.5 are well within the range      16 that can be explained by bias and confounding?</p> <p>17 MR. ROTMAN: Objection.</p> <p>18 A. I think all of the studies were      19 aware -- all of the authors were aware of      20 potential recall bias and confounding and sought      21 to control as much as possible those factors in      22 their control studies. Most of them, I feel,      23 were relatively well-designed to assess for and      24 adjust for multiple confounding factors.</p> <p>25 And as far as recall bias, there's an</p>	<p>1 that would ask that question because even asking      2 that question would potentially add an element of      3 recall bias --</p> <p>4 Q. But if a woman already --</p> <p>5 MR. TISI: She wasn't finished.</p> <p>6 Q. Were you finished?</p> <p>7 A. I was going to say in a lot of these      8 studies, they also asked about smoking history      9 and other potential lifestyle issues in addition      10 to talcum powder use that would -- and yet, those      11 types of questions didn't show an elevated risk      12 like talcum powder products.</p> <p>13 Q. Well, wouldn't you want to know --      14 before you interviewed the women who have ovarian      15 cancer, wouldn't you want to know if they have a      16 preconceived notion about what caused their      17 ovarian cancer so if you didn't exclude them from      18 the study, at least you could take that      19 preconceived bias into account when you did the      20 statistics?</p> <p>21 A. I would think if you're designing a      22 case-control study and trying to avoid recall      23 bias, there are better ways to do that because      24 just by asking, "Do you have a preconceived      25 notion about it?", you're introducing potential</p>

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1 bias because they might think, Oh, maybe there is 2 an association. And you're adding bias, 3 potentially, that way. 4 Q. You mentioned cigarette smoking just a 5 minute ago in response to Mr. Rotman's questions. 6 And you said cigarette smoking involves a 7 chronic inflammatory condition in the body; 8 correct? 9 A. There is an inflammatory response in 10 the body. 11 Q. But cigarette smoking has not been 12 shown to increase the risk of the two most common 13 forms of ovarian cancer, which is serous invasive 14 and endometrioid invasive; correct? 15 A. So, again, different tissues will 16 respond to different agents in different ways. 17 Mucinous carcinoma has been associated in some 18 studies with smoking, so there is evidence that 19 epithelial ovarian cancer can be caused by 20 smoking. 21 MR. KLATT: Object. Nonresponsive. 22 Q. The two most common forms of invasive 23 ovarian cancer -- serous, which is the most 24 common, and endometrioid, which is the second 25 most common -- have not been shown to be elevated	1 Yes. It involves an inflammatory state. 2 MR. KLATT: Thank you, Doctor. 3 MR. TISI: Just one question. 4 (Discussion off the record.) 5 MR. ROTMAN: We're done. 6 MR. TISI: Thank you. 7 THE VIDEOGRAPHER: Here ends today's 8 deposition. Off the record, 6:58 p.m. 9 (Deposition concluded at 6:58 p.m.) 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
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1 as a result of smoking; correct? 2 A. The data has not shown an association 3 between those two types with smoking. 4 Q. Even though smoking involves a chronic 5 inflammatory state; correct? 6 A. But, again -- 7 Q. That is -- did you hear my question? 8 Even though smoking involves a chronic 9 inflammatory state; correct? 10 A. We're talking about different types of 11 exposures. 12 Q. Does smoking -- 13 A. Different agent -- 14 MR. ROTMAN: One second, Mike. 15 Do you want an answer to the question? 16 Because you're cutting -- 17 BY MR. KLATT: 18 Q. My question is: Does smoking 19 involve -- 20 MR. ROTMAN: Wait. Wait, Mike. Let 21 her answer the question, and then you're done 22 because we're over. 23 Do you know what the question was? 24 A. Does smoking involve an inflammatory 25 state?	1 ----- 2 ----- 3 PAGE LINE CHANGE 4 _____ 5 REASON: _____ 6 _____ 7 REASON: _____ 8 _____ 9 REASON: _____ 10 _____ 11 REASON: _____ 12 _____ 13 REASON: _____ 14 _____ 15 REASON: _____ 16 _____ 17 REASON: _____ 18 _____ 19 REASON: _____ 20 _____ 21 REASON: _____ 22 _____ 23 REASON: _____ 24 _____ 25 REASON: _____

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1           ACKNOWLEDGMENT OF DEPONENT  
2

3           I, \_\_\_\_\_, do  
4           hereby certify that I have read the  
5           foregoing pages, and that the same  
6           is a correct transcription of the answers  
7           given by me to the questions therein  
8           propounded, except for the corrections or  
9           changes in form or substance, if any,  
10          noted in the attached Errata Sheet.  
11

12           \_\_\_\_\_  
13

14           SARAH E. KANE, M.D.         DATE  
15

16           \_\_\_\_\_  
17

18           \_\_\_\_\_  
19           Subscribed and sworn  
20           to before me this  
21           \_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_\_.  
22

23           My commission expires: \_\_\_\_\_  
24

25           \_\_\_\_\_  
Notary Public

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1           C E R T I F I C A T E  
2           COMMONWEALTH OF MASSACHUSETTS  
3           SUFFOLK, SS.

4           I, Janet M. Sambataro, a Registered Merit  
5           Reporter and a Notary Public within and for the  
6           Commonwealth of Massachusetts do hereby certify:

7           THAT SARAH E. KANE, M.D., the witness whose  
8           testimony is hereinbefore set forth, was duly sworn  
9           by me and that such testimony is a true and accurate  
10          record of my stenotype notes taken in the foregoing  
11          matter, to the best of my knowledge, skill and  
12          ability; that before completion of the deposition  
13          review of the transcript was requested.

14           I further certify that I am not related to any  
15           parties to this action by blood or marriage; and that  
16           I am in no way interested in the outcome of this  
17           matter.

18           IN WITNESS WHEREOF, I have hereunto set my hand  
19          this 28th day of January, 2019.

20

21           \_\_\_\_\_  
22           JANET M. SAMBATARO  
23           Notary Public

24           My Commission Expires:  
25           July 16, 2021